EPA REGISTRATION NUMBER 6836-387

PROCESSING REQUEST

Reg. #: 6836-387 **Decision #:** 541622

Description:

Material Sent (see jacket):

X New CSF(s) Dated: Basic: 11/14/18

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Joe Daniels

Division: Antimicrobials Division

Phone: (703) 347-8669 **Date:** 11/26/18

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
6836-387	11/26/18

Term of Issuance:
Conditional

Name of Pesticide Product:
NUGEN HD-64

Name and Address of Registrant (include ZIP Code):

Kathryn Rosario
Regulatory Assurance Specialist
Lonza Inc.
412 Mount Kemble Avenue
Morristown, NJ 07960

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

John Hebert, Chief
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Date:
11/26/18

EPA Form 8570-6

2. Be aware that proposed data requirements have been identified in a Work Plan. For more information on these proposed data requirements, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 6836-387."

4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/19/2018

If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

Enclosure

{Note to reviewer:
Items in brackets {AAA} are optional and may/may not be included on final label.
Items in braces {AAA} are for information purposes and will not appear on final label}

NUGEN 1ID-64

One-Step Germicidal† Cleaner and Deodorant

ACCEPTED
11/26/2018
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under
EPA Reg. No. 6836-387

DISINFECTANT
STAPHYLOCIDAL[1]
FUNGICIDAL
*VIRUCIDAL
PSEUDOMONACIDAL[2]
BACTERICIDAL
MILDEWSTATIC

[FLORAL] / [CITRUS] / [FRESH] / [CLEAN] / [LEMON] / [PINE] / [MINT] [scent] [fragrance] [odor] [scented]

Active Ingredients:	
Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate.....	3.03%
Other Ingredients:	96.97%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

POISON

See [left] [side] [right] [back] panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-XXX
EPA Est. No. (*as indicated on container*)
Net Contents (*as indicated on container*)

[*DOT symbols*]
[Country of origin (insert country)]
[Manufactured in (insert country)]
[*BARCODE*]

Manufactured by:
LONZA Inc.
412 Mount Kemble Avenue
Suite 200S
Morristown, NJ 07960

[1]*staphylococcus aureus and staphylococcus epidermis*

[2]*pseudomonas aeruginosa*

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER-POISON. Corrosive. Causes irreversible eye damage and skin burns. Fatal if absorbed through skin or inhaled. May be fatal if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear protective eyewear such as goggles, face shield, or safety glasses. Wear coveralls worn over long-sleeved shirt and long pants, socks and chemical-resistant boots, and waterproof gloves (Barrier Laminate, or Butyl Rubber, or Nitrile Rubber, or Neoprene Rubber, or Natural Rubber, or Poly-ethylene, or Polyvinyl Chloride (PVC), or Viton, selection Category A). Wear a minimum NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; or a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; or a NIOSH-approved powered air purifying respirator with HE filters. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact 1-800-222-1222, the poison control center, for emergency medical treatment information.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

{If container size is 5 gallons or larger, use the following Environmental Hazards statement:}

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

{Note to reviewer: the following is considered optional marketing language:}

A multi-purpose, germicidal† detergent effective in the presence of a moderate amount of organic soil (5% serum).

Bleach-free
Cleans, disinfects, and eliminates odors.
Continuous Odor Removal
[Deodorizes and] has a clean, fresh scent
Destroys [mold] odors at the source.
Disinfecting [Multi-Purpose] Cleaner
Disinfects [and / or] cleans [and / or] deodorizes in one [labor saving] step when used according to the directions for disinfection.
Doesn't just mask odors, it eliminates them.
Eliminates [smoke] [pet] [mold] odors.
Eliminates tough [floor] dirt and germs†
[Good for] [use on] finished wood surfaces
Help is on the way
Makes 65 gallons *{on the 1 gallon label}*
Meets OSHA Bloodborne Pathogen standard for HIV
Mold Odor Destroyer
Multi-purpose –or- Floor cleaner –and/or- disinfectant
No smeary residue
Odor counteractant

†***Note to reviewer:*** *If a supplemental label is using the "**Germs**" claim, per the EPA Guidance on use of the term "Germs" in order to make an unqualified "germ" claim the supplemental label must list all 3 of the major classes of organisms: Virus, Bacteria, Fungi and label must bear disinfectant directions. In order to make a qualified "germ" claim the supplemental label must be a broad spectrum disinfectant and list additional claims against one of the following two major classes of organisms: Fungi or Viruses and must bear disinfectant directions. The front panel of the label for a qualified claim must contain a designator [such as **] that refers the user to the qualified statements that describes the type of germ the product is efficacious against. An unqualified claim can appear on front or back panel and does not require a designator.*

{Note to reviewer: the following is considered optional marketing language:}

Use **NUGEN 1ID-64** in:
{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people animal or food will be depicted in graphics. Toy graphics will be submitted to Agency for review.}

Bathrooms
Homes [households]
Kitchens

Dental offices
Hospitals
Medical Offices [Clinics]
Nursing homes

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Federally inspected meat and poultry plants,
Food processing plants
Food storage areas
Institutional kitchens
Restaurants
[USDA] [Federally] inspected food processing facilities

Athletic facilities
Barber shops
Business and office buildings
Colleges
Correctional facilities
Dressing rooms
Exercise facilities
Factories
Hotels
Institutional facilities
Institutions
Locker rooms
Motels
Prisons

Public facilities
Public rest rooms
Schools
Shower and bath areas
Salons [Beauty]
Universities

Camp grounds
Play ground equipment
Animal laboratories

Dairy farms
Farms [Farm premises]
Hog farms
Kennels
Pet animal quarters
Pet shops
Poultry farms
Poultry houses
Turkey farms
Veterinary clinics
Zoos

Airplanes
Airports
Boats
Buses
Campers
Cars
Emergency vehicles
Mobile homes
Ships
Taxis
Trailers
Trains
Transportation terminals

{Note to reviewer: the following is considered optional marketing language:}

[TYPES OF SURFACES:]

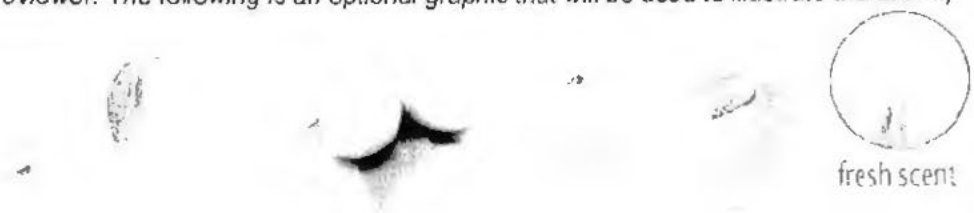
Use **NUGEN 1ID-64** on washable hard, nonporous surfaces of:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people, animal or food will be depicted in the graphics. Only exteriors of microwaves and refrigerators will be depicted.}

Appliances, exterior surfaces
Basins [empty]
Bathroom [lavatory] fixtures
Bathtubs
Cabinets
Cages
Chairs
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
Conductive flooring
Counters [countertops]
Desks
Doorknobs
Floors
Garbage cans
Highchairs
Kennel runs
Microwave ovens, exterior surfaces
Outdoor furniture
Refrigerators, exterior surfaces
Refrigerated storage and display equipment
Showers
Shower stalls
Sinks [bathroom, kitchen]
Stoves [stovetops]
Tables, [picnic tables]
Telephones
Toilets
Toilet bowls
Toilet bowl surfaces
Tubs
Tiles, glazed
Urinals
Walls

Other hard nonporous surfaces made of:
Formica®
Glazed ceramic
Glazed enameled surfaces
Glazed porcelain
Metal
Painted surfaces
Plastic (such as polystyrene or polypropylene)
Sealed stone
Stainless steel
Upholstery, vinyl and plastic
Woodwork, finished

Note to reviewer: The following is an optional graphic that will be used to illustrate the scent.}



** Formica® is a registered trademark of The Diller Corporation*

{Note to reviewer: The following are optional graphics that will be used to illustrate possible use sites.}

toilet
baño

garbage area
area de basura

shower
ducha

{Note to reviewer: The following are optional graphics that will be used to illustrate odors to be controlled.}

smoke
humo

mold & mildew
moho y hongos

pet carrier
portador del
animal domestico

{Note to reviewer: the following is considered optional marketing language:}

Effective [as a disinfectant] against the following pathogens.
[Bacteria:]
Enterobacter aerogenes (ATCC 13048)
Escherichia coli (ATCC 11229)
Klebsiella pneumonia (ATCC 4352)
Pseudomonas aeruginosa (ATCC 15442)
Salmonella enterica (ATCC 10708)
Serratia marcescens (ATCC 14756)
Shigella flexneri (ATCC 12022)
Shigella sonnei (ATCC 11060)
Staphylococcus aureus (ATCC 6538)
Staphylococcus aureus - Methicillin-Resistant [MRSA] (ATCC 700699)
Staphylococcus epidermidis (ATCC 12228)
Streptococcus pyogenes [Strep] (ATCC 19615)

[Viruses:]
*Herpes simplex Type 1 Virus [Herpes]
*Influenza A Virus [Influenza]
*HIV-1 [AIDS virus]

[Fungi:]
Trichophyton interdigitale [Athlete's Foot Fungus] [A Cause of ringworm]

DILUTION: 1:64 2 fl. oz. per gallon of water [474 ppm Active Quat]

{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}
***[AVISO:** SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.]*

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL USE DIRECTIONS

APPLICATION: For disinfection, remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 2 fl. oz. [1/4 cup] of the concentrate per 1 gallon of water. Apply with a cloth, mop, sponge, or coarse sprayer, or by soaking. For sprayer applications, use a coarse spray device. Spray 6-8-inches from surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface for a minimum of 10 minutes. Rinse or wipe dry with a clean cloth or sponge or allow to air dry.

Rinse all surfaces that come in contact with food such as countertops, exterior surfaces of appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes or appliance interior surfaces as a disinfectant.

Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

Rinsing of floors is not necessary unless they are to be waxed or polished.

{Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:}
This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.
{or}
This product is not for use on medical device surfaces.

{Note to reviewer: Alternate Directions for use:}
General Cleaning:
Mix 2 fl. oz. [1/4 cup] per 1 gallon of water.

To Disinfect and Clean [throughout your home]:
Mix 2 fl. oz. [1/4 cup] per 1 gallon of water. Let stand for a minimum of 10 minutes before wiping. For heavily soiled surfaces, a precleaning step is required.

For tough jobs.
Pour directly on sponge or soil. Let stand for a minimum of (contact time) before wiping. Rinse thoroughly with clean water.

For surfaces that may come in contact with food potable water rinse is required.

USDA: Use in federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, non-processing areas, and / or exterior areas.

USDA: For use in federally inspected meat and poultry plants as a floor and wall cleaner for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. All surfaces must be thoroughly rinsed with potable water.

TOILET BOWLS: To clean, apply diluted solution around the bowl and up under the rim. Stubborn stains may require brushing.

To disinfect, first preclean to remove heavy soil, then [remove or expel over the inner trap the residual bowl water] or [empty bowl]. Pour in 3 fl. oz. of the diluted solution. [Swab the bowl completely using a scrub brush or mop] [Brush bowl completely], making sure to get under the rim. Let stand for 10 minutes [or overnight], then flush.

DISINFECTION OF BARBER / BEAUTY / SALON INSTRUMENTS AND TOOLS: Tools (such as combs, brushes, razors, scissors, and other shop tools) can be disinfected by immersing in a 2 fl. oz. [1/4 cup] per 1 gallon solution for a contact time of at least 10 minutes. Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

FUNGICIDAL DIRECTIONS: NUGEN 1ID-64 is an effective fungicide against Trichophyton interdigitale [the athlete's foot fungus] [a cause of ringworm] in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Follow disinfection directions.

MILDEWSTATIC DIRECTIONS:
[Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops.] Apply solution [2 fl. oz. [1/4 cup] per 1 gallon of water] with a cloth, mop, sponge, or coarse sprayer, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application weekly or when growth reappears.

***KILLS HIV-1 [AIDS VIRUS] ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV1] [associated with AIDS].

Special Instructions for Cleaning and Decontamination Against *HIV-1 [*AIDS Virus] of Surfaces / Objects Soiled With Blood / Body Fluids.
Personal Protection: Clean-up must always be done wearing protective gloves, gowns, masks and eye protection.
Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of **NUGEN 1ID-64**.
Contact Time: Leave surface wet for 5 minutes [at 25°C] [77°F] [room temperature]. Use a 10-minute contact time for disinfection against all other viruses, fungi, and bacteria claimed.
Disposal of Infectious Materials: Blood, body fluids, cleaning materials and clothing must be disposed of according to federal, state, and local regulations for infectious waste disposal.

FARM PREMISE, LIVESTOCK, TURKEY AND POULTRY HOUSE DISINFECTANT:
1. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
2. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent, and rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, coops, cars, boats, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.
8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automated feeders, fountains, and waterers with soap and detergent, and rinse with potable water before reuse.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting hard, nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 oz. of **NUGEN 1ID-64** per 1 gallon of water *[or equivalent dilution]* for a period of 10 minutes. Wipe or allow to air dry. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

HEAVY-DUTY CLEANING INSTRUCTIONS:

Use [1 fl. oz. of **NUGEN 1ID-64** per 24 fl. oz. of water] [4 to 6 fl. oz. of **NUGEN 1ID-64** per 1 gallon of water] to clean heavily soiled areas.

{Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{or}

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

{Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for "All products in containers that could be burned," the registrant has the option to "Remain silent on burning;" therefore, no incineration language is provided for plastic containers.}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.
Pesticide Disposal:
Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
Container Disposal:
Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.
{Plastic and Metal Containers:} Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.
{For metal containers only:} DO NOT cut or weld metal containers.
{For Bag in Box Containers:} Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

{Note to reviewer: For Nonrefillable Sealed Containers: Packaging options can be in sealed containers or bottles designed for use dilution systems to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
Container Disposal: Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

Daniels, Joseph

From: Kathryn Rosario <kathryn.rosario@lonza.com>
Sent: Wednesday, November 21, 2018 5:18 PM
To: Daniels, Joseph
Subject: Re: EPA Reg. No. 6836-GIT, GIA

Can we address the phys/chem data that Vekalet has asked about when we address the tox issues? Thanks, Kathryn

Sent from my iPhone

On Nov 21, 2018, at 1:52 PM, Daniels, Joseph <Daniels.Joseph@epa.gov> wrote:

> I just listened to your voicemail. I talked to Vekalet, and she said she will try her best to have the review completed ASAP with the information you sent in taken into account.
>
> Joe
>
> **From:** Daniels, Joseph
> **Sent:** Wednesday, November 21, 2018 12:39 PM
> **To:** 'Kathryn Rosario' <kathryn.rosario@lonza.com>
> **Cc:** Miederhoff, Eric <Miederhoff.Eric@epa.gov>
> **Subject:** RE: EPA Reg. No. 6836-GIT, GIA
>
> Good afternoon. I will not be in the office Friday, but will start working on this right away. Thanks!
>
> Joe
>
> **From:** Kathryn Rosario <kathryn.rosario@lonza.com>
> **Sent:** Wednesday, November 21, 2018 12:33 PM
> **To:** Daniels, Joseph <Daniels.Joseph@epa.gov>
> **Cc:** Miederhoff, Eric <Miederhoff.Eric@epa.gov>; Tek, Vekalet <tek.vekalet@epa.gov>
> **Subject:** RE: EPA Reg. No. 6836-GIT, GIA
> **Importance:** High
>
> Joe,
>
> We will proceed with option 3. I have attached labels with language per pre-decisional determination.
>
> Regards,
> Kathryn
>
> **From:** Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
> **Sent:** Wednesday, November 21, 2018 10:28 AM
> **To:** Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>
> **Cc:** Miederhoff, Eric <Miederhoff.Eric@epa.gov>
> **Subject:** RE: EPA Reg. No. 6836-GIT, GIA

Good morning. We reviewed your response to your pre-decisional determination and have decided that we cannot review the newly cited studies before the end of the PRIA timeframe, which ends on Monday November 26th. This is not eligible for a renegotiation because the studies were not sent in with the original submission, and renegotiation is reserved for reviewing changes to the studies originally submitted. At this time, there are three options:

1) Withdrawal and resubmit new A540 PRIA application with revised acute toxicity data
2) Do-Not-Grant
3) Submit label with language per pre-decisional determination

A withdrawal and resubmittal would ensure an A540 PRIA timeframe. A do not grant does not cost any additional money, but does not ensure a concrete review time. If you submit labels with language per the pre-decisional determination, we can register the products. You could then submit the additional data as an A570 and A570.1 as opposed to A540s and save some time on the review. Please let us know as soon as possible how you wish to proceed.

Joe

From: Kathryn Rosario <kathryn.rosario@lonza.com>
Sent: Monday, November 19, 2018 10:25 AM
To: Miederhoff, Eric <Miederhoff.Eric@epa.gov>; Daniels, Joseph <Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA
Importance: High

Eric, Joe,

We have addressed the tox issues. The data matrix has been revised as follows:

•MRID 43649103 will be cited for acute dermal tox. We are requesting that the acute dermal be waived, and that the acute oral classification be used for Dermal, per *EPA Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations & Supporting Retrospective Analysis (November 9, 2016)*

•MRID 47426203 will be cited for acute inhalation tox.

We have revised the labels to include the respirator language in the Precautionary Statements section however the data that we have cited on the data matrix will allow to proceed with the label without the "poison" classification.

The correct Enforcement Analytical Method reference is also now on the data matrix – MRID 49445602.

I have attached CSFs – please note explanation below in reference to the pH range. If this is not acceptable, let me know and I will revise.
The pH (neat) is 8.38 per the report.
We round this up to 8.4 and take +/-5% of that number to arrive at the pH range of 8.0 to 8.8.
We typically prefer to provide a pH range instead of one pH value on the CSF because it's impossible to always get the same pH every time a batch is made due to very slight differences in manufacturing, raw materials, pH meters, etc.
Considering this, can we keep the range on the CSF?

Please contact me with any questions.

Regards,

Kathryn Rosario
Regulatory Assurance Specialist
Lonza Inc
412 Mt. Kemble Avenue. Suite 200S
US – 07960 Morristown. New Jersey
Tel. : +1 201 316 9288
Fax : +1 201 696 3483
mailto:kathryn.rosario@lonza.com
http://www.lonza.com

From: Miederhoff, Eric [mailto:Miederhoff.Eric@epa.gov]
Sent: Thursday, November 15, 2018 4:33 PM
To: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>
Cc: Daniels, Joseph <Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Hi Kathryn,

We still have till 11/26 for this PRIA, please let me know a projected delivery date for your response to the comments as quickly as possible and we can discuss next steps.

Regards,

Eric Miederhoff
Product Manager, Team 31
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-347-8028

From: Kathryn Rosario <kathryn.rosario@lonza.com>
Sent: Thursday, November 15, 2018 11:25 AM
To: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Cc: Daniels, Joseph <Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA
Importance: High

Eric,

We will need to renegotiate the PRIA date as we would like to address the acute tox review that you sent. I will send additional information as soon as possible, once I receive clarification from my colleagues in the Tox department.

Regards,
Kathryn

From: Miederhoff, Eric [mailto:Miederhoff.Eric@epa.gov]
Sent: Thursday, November 8, 2018 4:46 PM
To: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>; Daniels, Joseph

<Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Hi Kathryn,

Thank you for the additional materials. I have not had a chance to revise the amended label, and since tomorrow is the predecisional deadline and Joe and I are both out of the office, I included the efficacy issues in the attached predecisional letter. However, if you feel you have addressed all the comments, you do not need to do anything additional at this time. We did have some additional comments on the label and via the acute toxicity review, however, and so have included those in the predecisional determination.

Let me know if you would like to discuss these matters further. I will be back in the office on Tuesday.

Regards,

Eric Miederhoff
Product Manager, Team 31
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-347-8028

From: Kathryn Rosario <kathryn.rosario@lonza.com>
Sent: Thursday, November 08, 2018 4:28 PM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: FW: EPA Reg. No. 6836-GIT, GIA
Importance: High

I have attached the updated data matrices and the EAM, MRID 49445602.
I have also attached updated labels per your comments from the efficacy review dated 10/11/2018, and the date has been added to the label.
I will forward revised CSFs if you accept the justification on the pH range that I provided earlier today.

Regards,

Kathryn Rosario
Regulatory Assurance Specialist
Lonza Inc
412 Mt. Kemble Avenue, Suite 200S
PO Box 07960 Morristown, New Jersey
Tel +1 201 316 9288
Fax +1 201 696 3483
mailto:kathryn.rosario@lonza.com
http://www.lonza.com

From: Rosario Kathryn - Allendale
Sent: Thursday, November 8, 2018 11:55 AM
To: 'Daniels, Joseph' <Daniels.Joseph@epa.gov>
Cc: 'Miederhoff, Eric' <Miederhoff.Eric@epa.gov>
Subject: FW: EPA Reg. No. 6836-GIT, GIA
Importance: High

Joe, Eric,

In reference to my comments on the Enforcement Analytical Method below; the comment is incorrect and I will update the data matrix with the MRID number that we intend to cite for this.

Regards,
Kathryn

From: Rosario Kathryn - Allendale
Sent: Wednesday, November 7, 2018 3:59 PM
To: 'Daniels, Joseph' <Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Hi Joe,

Please see responses below.

Regards,
Kathryn

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Wednesday, October 31, 2018 7:29 AM
To: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Good morning. I just spoke with our chemistry reviewer who mentioned that she had spoken to you on the phone yesterday. She sent me a list of issues that need to be addressed:

1. The trade name of the active ingredient does not match with the Registration number, 6836-236, for the proposed Basic CSF, dated 05/31/2018 and the study(Guideline 830.1650, MRID#50597001). Carboquat H is an alternate brand name on file for the 6836-236.
2. **Data Evaluation Table [Guideline 830.1650]**

§830.1650(b)(3(ii); pertaining to characterization of the process The guideline for (b) (3) (ii) mentioned in 830.1650 references 830.1620 (b) (3) (ii). I do not see a (b) (3) (ii) listed in 830.1650 Guidelines. MRID 50597001 has listed guideline 830.1620 as not applicable on page 5 of the study.	**Not available**
§830.1650(b)(3(iv); pertaining to ingredients used to process (see **Deficiency#1**) The guideline for (b) (3) (iv) mentioned in 830.1650 references 830.1620 (b) (3) (iv). I do not see a (b) (3) (iv) listed in 830.1650	**Requires Upgrading**

Guidelines. MRID 50597001 has listed guideline 830.1620 as not applicable on page 5 of the study.	
§830.1650(b)(3(v); pertaining to process equipment	Satisfied
§830.1650(b)(3(v); pertaining to the conditions of the process **(such as pH, temperature, humidity, pressure, rpm)** The guideline for (b) (3) (v) mentioned in 830.1650 references 830.1620 (b) (3) (v). I do not see a (b) (3) (v) listed in 830.1650 Guidelines. MRID 50597001 has listed guideline 830.1620 as not applicable on page 5 of the study.	**Not available**
§830.1650(b)(3(v); pertaining to quality control measures	Satisfied

3. The date on the updated Basic CSF and Data Matrix, dated 05/31/2018, are not updated. They are provided to us on July 31, 2018. I will update and send you a revised CSF with the correct date.
4. There is no date on the proposed label. I will update the label and add the date. I am working on the other revisions that you requested for the label also.
5. Study for Guideline 830.1800, Enforcement Analytical Method is not available on the referred MRID#50597001(see the study and Data Matrix, dated 05/31/2018). The reference to EAM (830.1800) is was not intended to be included on the data matrix; it is not required for this end use product so I will need to amend the data matrix to remove it. Guideline 830.1800 was not included as part of MRID 50597001.
6. The pH range is used for the proposed Basic CSF, dated 05/31/2018. However, there is no justification provided. I need to ask my manager about the pH range and I will correct that also.
7. It is not clear whether the test substance, DS6771, and test Substance Identification#405-18B11QUat, for the accelerated storage stability and corrosion characteristic studies(Guidelines 830.6317 and 830.6320) can represent the proposed product(Nugen 1ID 64(MRID#50597004). I included in the cover letter an explanation of the test substances DS6771 as the Nugen 1ID formulation. The DS6771 name identifies the product before we have a name for the EPA registration during the testing phase.
   The names of the test substance used in these studies is not the requested EPA primary brand name. The table below describes the formulation of the Test Substance.

Test Substance ID	Formulation Name	EPA Reg. No.	CSF followed
DS 6771 Lot # 6070-014 Lot # 6066-180 and 6066-181	NUGEN 1ID-64	6836-*not yet assigned*	Basic

From: Daniels, Joseph
Sent: Friday, October 26, 2018 12:37 PM
To: 'Kathryn Rosario' <kathryn.rosario@lonza.com>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Good morning. Please see the attached efficacy review for 6836-GIA and -GIT. I will send along the acute toxicity and product chemistry reviews as soon as they are completed. Please let me know if you have any questions.

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Wednesday, August 8, 2018 4:31 PM

To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

I have attached the data matrix for the 6836-GIA

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Wednesday, August 08, 2018 4:02 PM
To: Rosario Kathryn - Allendale
Cc: Miederhoff, Eric
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Good afternoon. Thank you for getting back to us on this. I know they will be using the same data, but can you please submit a data matrix for the secondary registration as well? Thanks!

Joe

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Wednesday, August 8, 2018 3:22 PM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Hi Joe,

In reference to our conference call on Monday, please see attached. The data matrix is revised as well. Let me know if you have any questions or need more information.

Regards,
Kathryn Rosario
Regulatory Assurance Specialist
Regulatory
Lonza Inc
90 Boroline Rd
US - 07401 Allendale
Tel : +1 201 316 9288
Fax : +1 201 696 3483
mailto:kathryn.rosario@lonza.com
http://www.lonza.com

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Thursday, August 02, 2018 10:51 AM
To: Walsh Jonathan - Allendale
Cc: Rosario Kathryn - Allendale; Miederhoff, Eric
Subject: RE: EPA Reg. No. 6836-GIT, GIA

That works. Please see below for the conference call information.

Conference number: 202-991-0477
Conference ID: 8647776

From: Jonathan Walsh [mailto:jonathan.walsh@lonza.com]
Sent: Thursday, August 2, 2018 10:46 AM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Kathryn Rosario <kathryn.rosario@lonza.com>; Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Could we meet at 1:00 on Monday?

Regards,
Jonathan

(p) 201 316 9327
(m) 201 675 6326
jonathan.walsh@lonza.com

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Thursday, August 02, 2018 10:41 AM
To: Walsh Jonathan - Allendale <jonathan.walsh@lonza.com>
Cc: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>; Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

We are free any time Monday afternoon before 4:30pm, and between 9:00-10:00am or 3:00-4:30pm on Tuesday.

Joe

From: Jonathan Walsh [mailto:jonathan.walsh@lonza.com]
Sent: Thursday, August 2, 2018 10:34 AM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Kathryn Rosario <kathryn.rosario@lonza.com>; Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Good Morning Joe,

Thanks for getting back so promptly. Please let me know what times work best for you on Monday or Tuesday next week.

Regards,
Jonathan

(p) 201 316 9327
(m) 201 675 6326
jonathan.walsh@lonza.com

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Thursday, August 02, 2018 7:22 AM
To: Walsh Jonathan - Allendale <jonathan.walsh@lonza.com>
Cc: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>; Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: EPA Reg. No. 6836-GIT, GIA

Good morning Jonathan. I just got your message from yesterday afternoon. Is there a time this afternoon or early next week that you two would be available for a conference call to discuss these two actions? We would be free between 2:00 and 3:00pm, and 4:00-4:30pm today, and are pretty open on Monday.

Joe Daniels
Environmental Protection Specialist
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 347-8669
<image001.png>

This communication and its attachments, if any, may contain confidential and privileged information the use of which by other persons or entities than the intended recipient is prohibited. If you receive this transmission in error, please contact the sender immediately and delete the material from your system.

This communication and its attachments, if any, may contain confidential and privileged information the use of which by other persons or entities than the intended recipient is prohibited. If you receive this transmission in error, please contact the sender immediately and delete the material from your system.

This communication and its attachments, if any, may contain confidential and privileged information the use of which by other persons or entities than the intended recipient is prohibited. If you receive this transmission in error, please contact the sender immediately and delete the material from your system.

This communication and its attachments, if any, may contain confidential and privileged information the use of which by other persons or entities than the intended recipient is prohibited. If you receive this transmission in error, please contact the sender immediately and delete the material from your system.

This communication and its attachments, if any, may contain confidential and privileged information the use of which by other persons or entities than the intended recipient is prohibited. If you receive this transmission in error, please contact the sender immediately and delete the material from your system.

This communication and its attachments, if any, may contain confidential and privileged information the use of which by other persons or entities than the intended recipient is prohibited. If you receive this transmission in error, please contact the sender immediately and delete the material from your system.

Daniels, Joseph

From: Kathryn Rosario <kathryn.rosario@lonza.com>
Sent: Wednesday, August 1, 2018 1:03 PM
To: Daniels, Joseph
Cc: Miederhoff, Eric
Subject: RE: EPA Reg. No. 6836-GIT, -GIA

Joe,

Ok, I will send a copy of the waiver as soon as possible. We will get back to you shortly on scheduling a conference call.

Thanks,
Kathryn

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Tuesday, July 31, 2018 4:07 PM
To: Rosario Kathryn - Allendale
Cc: Miederhoff, Eric
Subject: RE: EPA Reg. No. 6836-GIT, -GIA

Good afternoon. Thank you your response. The waiver should suffice for skin sensitization, but can you please submit a copy of the actual waiver? We still cannot accept your rationales behind the rest of your acute tox data. Once again, a large list of products with a similar AI does not help us deal with product specific data. We still need to have a specific product to cite to or a cite all to address product specific data. I'd be happy to schedule a conference call to discuss as it may be better to talk about it in real time.

Joe

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Tuesday, July 31, 2018 9:50 AM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, -GIA

Hi Joe,

I have attached revised data matrix for both 6836-GIT and 6836-GIA and the corrected CSF for 6836-GIT.
Please note that we have corrected the citation for eye irritation on these data matrices. Footnote 2 has also been corrected to cite the DDAC DCI case 3003.
Per OPP's Guidance for Waiving or Bridging of Mammalian Acute Toxicity Tests for Pesticides and Pesticide Products, we are requesting a waiver for the skin sensitization because the product is corrosive. If you need a formal letter in reference to the waiver, please let me know.
We believe that the data as cited on the matrices should satisfy the requirements for acute tox for these products, according to EPA Batching of End-Use Products for Meeting Acute Toxicological Data Requirements. If you feel there is still a discrepancy in this area, we will certainly address it!

Regards,

Kathryn Rosario
Regulatory Assurance Specialist
Regulatory
Lonza Inc
[illegible]
[illegible] Allendale
Tel [illegible]
Fax [illegible]
mailto:kathryn.rosario@lonza.com
http://www.lonza.com

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Tuesday, July 31, 2018 7:37 AM
To: Rosario Kathryn - Allendale
Cc: Miederhoff, Eric
Subject: RE: EPA Reg. No. 6836-GIT, -GIA

Good morning. I just have a couple small issues to bring up with the chemistry technical screen for these two products. The CSF for -GIT (Nugen 1ID-64) is marked as an alternate formulation rather than basic. Please also provide a data matrix for the secondary registration, even if it is the same as the primary. Lastly, please let me know if you have any questions concerning the e-mail below this on sent on July 27th.

Joe

From: Daniels, Joseph
Sent: Friday, July 27, 2018 4:15 PM
To: 'Kathryn Rosario' <kathryn.rosario@lonza.com>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT

Yes, but the source contains more than just the active ingredient and water. If you can refer to a product with the same source product with a similar concentration of water (or a source with a similar composition), that should work.

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Friday, July 27, 2018 4:02 PM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT

Hi Joe,

The only additional ingredient in this product is water and that should not affect the acute tox profile?

Thanks,
Kathryn

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Friday, July 27, 2018 3:47 PM
To: Rosario Kathryn - Allendale
Cc: Miederhoff, Eric
Subject: RE: EPA Reg. No. 6836-GIT

Good afternoon. It appears as if this would help to address generic data on the active ingredient, but not product specific data. There are more ingredients in your product than just the active ingredient, and all are important in determining the acute tox profile. Therefore, this does not address the issues found in the acute toxicity technical screen.

Joe

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Friday, July 27, 2018 10:35 AM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT

Joe,

I discussed with my manager and he provided this document which explains on page 5 (below) the applicability of this data for this product:

Quaternary Ammonium Compounds

DDACB is a part of the Group I class (cluster I grouping) establish
a member of the aliphatic dimethyl dialkyl quaternary ammonium

Didecyl dimethyl ammonium chloride (DDAC) which has been ree
case #3003 is the representative member of the Group I class of qu
compounds. Hazard data generated for DDAC is considered to be r
associated with all chemicals assigned to this class of quaternary ar
including DDACB. Consequently, human health toxicity studies c
Group I class quaternary ammonium compounds can be bridged in
toxicity data base. The DDACB risk assessments will be based on
DDAC/DDACB combined database.

Please let me know if you need more information!

Regards,
Kathryn

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Thursday, July 26, 2018 9:46 AM
To: Rosario Kathryn - Allendale
Cc: Miederhoff, Eric
Subject: RE: EPA Reg. No. 6836-GIT

I apologize, I was not very clear. The document that I am referring to is the MRID 48877801 that was used to satisfy acute toxicity.

Joe

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Thursday, July 26, 2018 8:57 AM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT

Hi Joe,

What document is it that is not correct? Is it the 8570-34 data citation form?

Thanks,
Kathryn

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Thursday, July 26, 2018 8:26 AM
To: Rosario Kathryn - Allendale
Cc: Miederhoff, Eric
Subject: EPA Reg. No. 6836-GIT

Good morning. I was just informed by our reviewer that the document provided with your acute toxicity package does not adequately address the data requirements. Per A540 guidance, your data may be addressed through the cite all method, selective data citation, or through data waivers. Please let me know if you have any questions.

Joe

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Tuesday, July 24, 2018 4:08 PM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: 6836-GIT: PRIA TRACKING MILESTONE # 3

No, we do not need the current primary brand names to be listed as ABNs. I will send you the revised documentation. Thanks for your assistance!

Regards,
Kathryn

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Tuesday, July 24, 2018 4:05 PM
To: Rosario Kathryn - Allendale
Cc: Miederhoff, Eric
Subject: RE: 6836-GIT: PRIA TRACKING MILESTONE # 3

Hello again. I just discussed this with Eric, and it should be fine to change them now, we'll just need revised labels and documentation. Would you like the current primary brand names to be alternate brand names?

Joe

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Tuesday, July 24, 2018 3:58 PM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: 6836-GIT: PRIA TRACKING MILESTONE # 3

Joe,

Ok. Would it be too much trouble to have these as the primary names instead? If so, I understand but I had to ask.

Thanks,
Kathryn

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Tuesday, July 24, 2018 3:23 PM
To: Rosario Kathryn - Allendale
Cc: Miederhoff, Eric
Subject: RE: 6836-GIT: PRIA TRACKING MILESTONE # 3

Good afternoon. I just went ahead and put them in as ABNs for now if that's okay. This e-mail can serve as our record for adding the names. Please let me know if you need anything else.

Joe

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Tuesday, July 24, 2018 3:05 PM
To: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Cc: Daniels, Joseph <Daniels.Joseph@epa.gov>
Subject: FW: 6836-GIT: PRIA TRACKING MILESTONE # 3

Hello,

I have been asked by my colleagues to check with EPA on these pending registrations, in reference to changing the product name. Are we able to do that during the review process?

The new names for the products would be as follows:

6836-GIT : NUGEN IID-64

6836-GIA : NUGEN IID-32

I would revise the submission documents to match these names. Just let me know. Otherwise, we will wait and file for alternate brand names.

Thank you,

Kathryn Rosario
Regulatory Assurance Specialist
Regulatory
Lonza Inc
90 Boroline Rd
Allendale
Tel: +1 201 316 9286
Fax: +1 201 596 3483
mailto:kathryn.rosario@lonza.com
http://www.lonza.com

From: PRIARegistrationTracking@epa.gov [mailto:PRIARegistrationTracking@epa.gov]
Sent: Monday, June 18, 2018 3:19 PM
To: Rosario Kathryn - Allendale
Cc: daniels.joseph@epa.gov
Subject: Spam: 6836-GIT: PRIA TRACKING MILESTONE # 3

Email: kathryn.rosario@lonza.com

Your application has been assigned to the following product manager (PM):

Name: Eric Miederhoff
Phone #: 703-347-8028
Email Address: Miederhoff.Eric@epa.gov

File Symbol/Reg #	Product Name	Decision #	PRIA Category	Fee for Service	Start Dt	PRIA Due Dt
6836-GIT	Nugen Valu...	541622	A540	25-JUN-18		26-NOV-18
6836-GIA	Nugen Valu...	541623	A540.1	25-JUN-18		26-NOV-18

The data associated with your application have been sent into review.

Date data sent into review: 06/18/2018

This is an automated email; please do not try to respond to it. Contact the PM identified above for any questions you might have.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA Office of Pesticide Programs

MEMORANDUM

11/23/2018

SUBJECT: Product Chemistry Review for **Nugen 1ID-64** EPA Reg. No.: **6836-GIT**

FROM: Vekalet Tek, Ph.D.
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Eric Miederhoff, PM Team 31 / Joseph Daniels
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: Lonza, Inc.
Action code: A540
Agency Due Date: 11/26/2018
DP No.: 447579
Submission No.: 1020662
E-Sub No.: 29741
Classification: EP
Process: Nonintegrated system
Pesticide type: Antimicrobial

MRID(s):50597001, 50597002, 50597003, 50597004

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
069208	148788-55-0 and 148812-65-1	Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate	3.03
		Other Ingredients	96.97
		Total	100%
Comments/Molecular Structure			

I. BACKGROUND

The Registrant, Lonza, Inc., has submitted an application for pesticide registration for their product: Nugen 1ID-64 EPA Reg. No. 6836-GIT and requested a review of the proposed Basic CSF, dated 11/19/2018, and Group A and Group B data.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-27 – Formulator's Exemption Statement	☒	☐
EPA FORM 8570-35 – Data Matrix (5/29/2018) and (11/19/2018)	☒	☐
Cover letter (6/1/2018)	☒	☐
Transmittal document	☒	☐
Proposed CSF BASIC, (5/31/2018) and (11/19/2018)	☒	☐
Proposed label, (11/19/2018) and (11/21/2018)	☒	☐
Certification for Pilot Fragrance Notification Program	☐	☒
	☐	☐
REFERENCED: CSF N/A , (N/A)	--	
Comments:		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	☐	☐	☒	☐	☒
Integrated	☐	☐	☐	☐	☐

Active Ingredients(s)	Nominal	Upper limit	Lower limit
Didecyl dimethyl ammonium carbonate/Didecyl dimethyl ammonium bicarbonate	3.03%	3.18%	2.88%

	YES	NO	N/A
1. The certified limits of all ingredients are within 40 CFR standard certified limits.	☒	☐	☐
2. Wider certified limits were requested and rationale was accepted.	☐	☐	☒

3. The nominal concentration(s) of the active ingredient is in agreement with the label.	☒	☐	☐
4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data(**The justification for the pH range for the proposed Basic CSF, dated 11/19/2018, is accepted, herein(see attached e-mails, dated 11/08/2018 and 11/19/2018).**	☐	☒	☐
5. All inert ingredients are approved for non-food use pesticide formulations.	☒	☐	☐
6. The impurities present >0.1% are identified.	☐	☐	☒
7. Impurities of toxicological significance have an upper certified limit.	☐	☐	☒

b. Product Label:

	Yes	NO	N/A
The formula contains one of the following:			
1. 10% or more of petroleum distillate	☐	☒	☐
2. 1.0% or more of methyl alcohol	☐	☒	☐
3. Sodium nitrite at any level	☐	☒	☐
4. A toxic list 1 inert at any level	☐	☒	☐
5. Arsenic in any form	☐	☒	☐
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	☐	☐	☒
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	☐	☐	☒
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	☒	☐	☐
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	☐	☒	☐

IV. Additional Findings

1. The Data Matrix, dated 05/31/2018, is revised and superseded by the updated Data Matrix, dated 11/19/2018.
2. The previously submitted labels (no date) and dated 11/19/2018, are revised and superseded by the updated label, dated 11/21/2018.
3. The name for the product, Nugen Value CQ 64, is updated to Nugen 1ID 64 for the updated Basic CSF and Data Matrix, dated 05/31/2018.

4. The test substance, DS6771 and the test substance identification: 405-18811QUat, for Group B studies represents the proposed product, Reg.# 6836-GIT, namely Nugen 1ID- 64 (MRID#50597002, 50597003, 50597004)(See attached e-mail, dated 10/31/2018).
5. Basic CSF, dated 05/31/2018 (provided to us on July 31, 2018), is corrected and superseded by the proposed Basic CSF, dated 11/19/2018.
6. Basic CSF, dated 05/31/2018(provided to us on July 31, 2018) and 11/19/2018, is accepted.

Table 1. Data Evaluation (Description of Formulation Process, Guideline 830.1650, MRID #50597001)

§830.1650(b)(3(ii); pertaining to characterization of the process	**Not available**
§830.1650(b)(3(iv); pertaining to ingredients used to process (see **IV. Additional Finding#1**)	**Requires Upgrading**
§830.1650(b)(3(v); pertaining to process equipment	Satisfied
§830.1650(b)(3(v); pertaining to the conditions of the process (**such as pH, temperature, humidity, pressure, rpm**)	**Not available**
§830.1650(b)(3(v); pertaining to quality control measures	Satisfied

Table 2: Accelerated Storage Stability at 54±2 °C (Guideline §830.6317, MRID# 50597004)

Test Substance Identification: 40S-18B11QUat

Procedure	Time Interval	
	Day zero (Control)	**Day 14**
Mean % By Weight of A.I. (Didecyl Dimethyl Ammonium Carbonate/Didecyl Dimethyl Ammonium Bicarbonate)	3.08	3.06

According to the study report(MRID#50597004): "This study showed that the test substance, DS6771, in the same type of container used for commercial sale of the product (HDPE with polypropylene closure) is stable under the accelerated storage condition of 54±2 °C for 14 days.". A visual inspection (the test substance and the container are visually inspected for any physical changes such as discoloration and deterioration) of the test substance showed no physical changes in the product over the test period. The storage container showed no physical changes but slight yellowing over the test period. Note: The analytical method(HPLC) for the quantification of the A.I. in the test substance for the detection of the storage stability of the product is validated with respect to linearity, precision, accuracy and specificity.

V. Conclusion

The Product Science Branch of The Antimicrobials Division finds, the proposed Basic CSF, dated, 11/19/2018, to **be acceptable**. Group A Data have been met with the exception of Description of formulation process (Guideline 830.1650) (see **VI. Table A: Series 830 guidelines – Group A**). Group B data have been met.

VI. Table A:

Series 830 guidelines – Group A

OPPTS#	Name	Status	MRID
830.1550	Product Identity & Composition	Acceptable	50597001
830.1600	Description of materials	Acceptable	50597001
830.1620	Description of production process	Not applicable, non-integrated	N/A
830.1650	Description of formulation process	**Requires upgrading(see IV. Additional Findings, Table 1.)**	50597001
830.1670	Discussion of formation of impurities	Not applicable, non-integrated	50597001
830.1700	Preliminary analysis	Not applicable, non-integrated	50597001
830.1750	Certified limits	Acceptable	50597001
830.1800	Enforcement analytical method	Acceptable	50597004 and 49445602
830.1900	Submittal of samples	Acceptable-"Samples will be submitted upon request"(Data Matrix, dated 05/31/2018)	50597001

VII. Table B: Series 830 guidelines – Group B

OPPTS#	Name	Study Findings/Comment	Status	MRID
830.6302	Color	Not required for end use product	Not applicable	N/A
830.6303	Physical state	Liquid at 20.8 oC	Acceptable	50597002
830.6304	Odor	Not required for end use product	Not applicable	N/A
830.6313	Stability to normal & elevated temperatures, metals & metal ions	The product is not TGAI	Not applicable	N/A
830.6314	Oxidation/Reduction	No oxidizer/reducer present	Acceptable	50597003
830.6315	Flammability	Avarage FlashPoint: 99.5 oC=212.1 oF	Acceptable	50597002
830.6316	Explodability	Product does not contain explosive ingredients	Acceptable	50597003
830.6317	Storage stability	The Accelerated Storage Stability Study at 54±2 oC for 14 days for the test substance, DS6771, is completed.	Acceptable	50597004
830.6319	Miscibility	Product not mixed with organic solvents	Acceptable	50597003
830.6320	Corrosion characteristics	The Accelerated Corrosion Characteristics Study at 54±2 oC for 14 days for the test substance, DS6771, is completed.	Acceptable	50597004
830.6321	Dielectric breakdown voltage	Product not used near electrical equipment	Acceptable	50597003
830.7000	pH	The average pH of a 1% aqueous solution of the test substance, DS6771: 9.06 at an average temperature 21.4 oC. The average pH of the neat test substance, DS6771: 8.38 at an average temperature 21.4 oC.	Acceptable	50597002
830.7050	UV/Visible absorption	Not required for MUP or EP	Not applicable	N/A
830.7100	Viscosity/Kinematic	1.15 cSt. At 25 oC (at 50 oC, the viscosity of the test substance is too low)	Acceptable	50597002

830.7200	Melting point	Not required for MUP or EP	Not applicable	N/A
830.7220	Boiling point	Not required for MUP or EP	Not applicable	N/A
830.7300	Density/relative	0.9978 g/ml at 20 oC	Acceptable	50597002
830.7370	Dissociation constants in water	Not required for MUP or EP	Not applicable	N/A
830.7520	Particle size	Not required for MUP or EP	Not applicable	N/A
830.7550/ 7560/ 7570	Partition coefficient	Not required for MUP or EP	Not applicable	N/A
830.7840/ 7860	Water solubility	Not required for MUP or EP	Not applicable	N/A
830.7950	Vapor pressure	Not required for MUP or EP	Not applicable	N/A

CONFIDENTIAL APPENDIX

PM NOTE:

1. The trade name of the active ingredient on the proposed Basic CSF, dated 11/19/2018, and study (Guideline 830.1650, MRID#50597001) does not match with the Registration number, 6836-236. Additionally, the listed trade name for the active ingredient on the proposed Basic CSF above is not listed as an alternate brand name in our database (BARDAC 22C50)(see the attached e-mail from the registrant, dated 11/07/2018). However, the supporting document provided by the registrant shows that the two different alternate brand names for 6836-236 were previously accepted by EPA (see attached letter, dated 10/30/2008).
2. The alternate brand name, carboquat, used for the active ingredient on the proposed Basic CSF, dated 11/19/2018, is not available on the proposed label, dated 11/21/2018.

Tek, Vekalet

From: Daniels, Joseph
Sent: Wednesday, November 07, 2018 4:26 PM
To: Tek, Vekalet
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Great, thanks! Sorry that it took so long to hear back from them.

From: Tek, Vekalet
Sent: Wednesday, November 7, 2018 4:25 PM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>; Hicks, Karen <Hicks.Karen@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Hello Joe,

Thank you for the update. Since you said you hadn't heard from the registrant, I completed the drafts and uploaded to SharePoint for Karen's approval last week.

Thank You!

Vekalet Tek

Vekalet Tek Ph.D
Chemist
Antimicrobials Division/ Product Science Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Penn.Ave , NW (7510P)
Washington, D.C. 20460
E-mail: tek.vekalet@epa.gov
Office Phone:703-347-8160

Street Address:
2777 Crystal Dr.
Arlington, VA 22202

From: Daniels, Joseph
Sent: Wednesday, November 07, 2018 4:20 PM
To: Tek, Vekalet <tek.vekalet@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: FW: EPA Reg. No. 6836-GIT, GIA

Good afternoon! I just received this response from the registrant (below in red). We are nearing the end of the PRIA clock on this one, so hopefully we can resolve it quickly. I will be out of the office until the 19th, so please work with Eric on this until then. Thanks!

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OCT 3 0 2008

Georgia Anastasiou
Agent for Lonza, Inc.
Lewis & Harrison
122 C Street, NW
Suite 740
Washington, DC 20001

Subject: Bardac 22C50
EPA Registration No.: 6836-236
Notification Date: October 1, 2008
EPA Receipt Date: October 2, 2008

Dear Ms. Anastasiou,

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA section 3(c)9 and PR Notice 98-10.

- Alternate Brand Names

General Comment

Based on a review of the submitted materials, your notification for the alternate brand names, Carboquat H and Carboquat HI &l, are acceptable and apart of the records on file.

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416 or Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Tek, Vekalet

From: Kathryn Rosario <kathryn.rosario@lonza.com>
Sent: Wednesday, November 21, 2018 12:33 PM
To: Daniels, Joseph
Cc: Miederhoff, Eric; Tek, Vekalet
Subject: RE: EPA Reg. No. 6836-GIT, GIA
Attachments: NUGEN 11D-32 Draft Label 20181121.pdf; NUGEN 11D-64 Draft Label 20181121.pdf

Importance: High

Joe,

We will proceed with option 3. I have attached labels with language per pre-decisional determination

Regards
Kathryn

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Wednesday, November 21, 2018 10:28 AM
To: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Good morning. We reviewed your response to your pre-decisional determination and have decided that we cannot review the newly cited studies before the end of the PRIA timeframe, which ends on Monday November 26th. This is not eligible for a renegotiation because the studies were not sent in with the original submission, and renegotiation is reserved for reviewing changes to the studies originally submitted. At this time, there are three options:

1) Withdrawal and resubmit new A540 PRIA application with revised acute toxicity data
2) Do-Not-Grant
3) Submit label with language per pre-decisional determination

A withdrawal and resubmittal would ensure an A540 PRIA timeframe. A do not grant does not cost any additional money, but does not ensure a concrete review time. If you submit labels with language per the pre-decisional determination, we can register the products. You could then submit the additional data as an A570 and A570.1 as opposed to A540s and save some time on the review. Please let us know as soon as possible how you wish to proceed.

Joe

From: Kathryn Rosario <kathryn.rosario@lonza.com>
Sent: Monday, November 19, 2018 10:25 AM
To: Miederhoff, Eric <Miederhoff.Eric@epa.gov>; Daniels, Joseph <Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA
Importance: High

Eric, Joe,

We have addressed the tox issues. The data matrix has been revised as follows

•MRID 43649103 will be cited for acute dermal tox. We are requesting that the acute dermal be waived, and that the acute oral classification be used for Dermal, per *EPA Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations & Supporting Retrospective Analysis (November 9, 2016)*

•MRID 47426203 will be cited for acute inhalation tox

We have revised the labels to include the respirator language in the Precautionary Statements section however the data that we have cited on the data matrix will allow to proceed with the label without the "poison" classification.

The correct Enforcement Analytical Method reference is also now on the data matrix – MRID 49415602.

I have attached CSFs – please note explanation below in reference to the pH range. If this is not acceptable, let me know and I will revise.
The pH (neat) is 8.38 per the report.
We round this up to 8.4 and take +/-5% of that number to arrive at the pH range of 8.0 to 8.8.
We typically prefer to provide a pH range instead of one pH value on the CSF because it's impossible to always get the same pH every time a batch is made due to very slight differences in manufacturing, raw materials, pH meters, etc.
Considering this, can we keep the range on the CSF?

Please contact me with any questions

Regards,

mailto:kathryn.rosario@lonza.com
http://www.lonza.com

From: Miederhoff, Eric [mailto:Miederhoff.Eric@epa.gov]
Sent: Thursday, November 15, 2018 4:33 PM
To: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>
Cc: Daniels, Joseph <Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Hi Kathryn,

We still have till 11/26 for this PRIA, please let me know a projected delivery date for your response to the comments as quickly as possible and we can discuss next steps.

Regards,

Eric Miederhoff
Product Manager, Team 31
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-347-8028

From: Kathryn Rosario <[redacted]>
Sent: Thursday, November 15, 2018 11:25 AM
To: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Cc: Daniels, Joseph <Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA
Importance: High

Eric

We will need to renegotiate the PRIA date as we would like to address the acute tox review that you sent. I will send additional information as soon as possible, once I receive clarification from my colleagues in the Tox department

Regards,
Kathryn

From: Miederhoff, Eric [mailto:Miederhoff.Eric@epa.gov]
Sent: Thursday, November 8, 2018 4:46 PM
To: Rosario Kathryn - Allendale <[redacted]>; Daniels, Joseph <[redacted]>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Hi Kathryn,

Thank you for the additional materials. I have not had a chance to revise the amended label, and since tomorrow is the predecisional deadline and Joe and I are both out of the office, I included the efficacy issues in the attached predecisional letter. However, if you feel you have addressed all the comments, you do not need to do anything additional at this time. We did have some additional comments on the label and via the acute toxicity review, however, and so have included those in the predecisional determination.

Let me know if you would like to discuss these matters further. I will be back in the office on Tuesday.

Regards,

Eric Miederhoff
Product Manager, Team 31
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-347-8028

From: Kathryn Rosario <[redacted]>
Sent: Thursday, November 08, 2018 4:28 PM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: FW: EPA Reg. No. 6836-GIT, GIA
Importance: High

I have attached the updated data matrices and the EAM, MRID 49445602.
I have also attached updated labels per your comments from the efficacy review dated 10/11/2018, and the date has been added to the label.
I will forward revised CSFs if you accept the justification on the pH range that I provided earlier today.

Regards,

[illegible]

From: Rosario Kathryn - Allendale
Sent: Thursday, November 8, 2018 11:55 AM
To: 'Daniels, Joseph' <Daniels.Joseph@epa.gov>
Cc: 'Miederhoff, Eric' <Miederhoff.Eric@epa.gov>
Subject: FW: EPA Reg. No. 6836-GIT, GIA
Importance: High

Joe, Eric,

In reference to my comments on the Enforcement Analytical Method below: the comment is incorrect and I will update the data matrix with the MRID number that we intend to cite for this.

Regards,
Kathryn

From: Rosario Kathryn - Allendale
Sent: Wednesday, November 7, 2018 3:59 PM
To: 'Daniels, Joseph' <Daniels.Joseph@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Hi Joe,

Please see responses below.

Regards,
Kathryn

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Wednesday, October 31, 2018 7:29 AM
To: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>

Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Good morning. I just spoke with our chemistry reviewer who mentioned that she had spoken to you on the phone yesterday. She sent me a list of issues that need to be addressed:

1. The trade name of the active ingredient does not match with the Registration number, 6836-236, for the proposed Basic CSF, dated 05/31/2018 and the study(Guideline 830.1650, MRID#50597001). Carboquat H is an alternate brand name on file for the 6836-236
2. **Data Evaluation Table [Guideline 830.1650]**

§830.1650(b)(3(ii); pertaining to characterization of the process The guideline for (b) (3) (ii) mentioned in 830.1650 references 830.1620 (b) (3) (ii). I do not see a (b) (3) (ii) listed in 830.1650 Guidelines. MRID 50597001 has listed guideline 830.1620 as not applicable on page 5 of the study.	**Not available**
§830.1650(b)(3(iv); pertaining to ingredients used to process (see **Deficiency#1**) The guideline for (b) (3) (iv) mentioned in 830.1650 references 830.1620 (b) (3) (iv). I do not see a (b) (3) (iv) listed in 830.1650 Guidelines. MRID 50597001 has listed guideline 830.1620 as not applicable on page 5 of the study.	**Requires Upgrading**
§830.1650(b)(3(v); pertaining to process equipment	Satisfied
§830.1650(b)(3(v); pertaining to the conditions of the process (such as pH, temperature, humidity, pressure, rpm) The guideline for (b) (3) (v) mentioned in 830.1650 references 830.1620 (b) (3) (v). I do not see a (b) (3) (v) listed in 830.1650 Guidelines. MRID 50597001 has listed guideline 830.1620 as not applicable on page 5 of the study.	**Not available**
§830.1650(b)(3(v); pertaining to quality control measures	Satisfied

3. The date on the updated Basic CSF and Data Matrix, dated 05/31/2018, are not updated. They are provided to us on July 31, 2018. I will update and send you a revised CSF with the correct date.
4. There is no date on the proposed label. I will update the label and add the date. I am working on the other revisions that you requested for the label also.
5. Study for Guideline 830.1800, Enforcement Analytical Method is not available on the referred MRID#50597001(see the study and Data Matrix, dated 05/31/2018). The reference to EAM (830.1800) is was not intended to be included on the data matrix; it is not required for this end use product so I will need to amend the data matrix to remove it. Guideline 830.1800 was not included as part of MRID 50597001.
6. The pH range is used for the proposed Basic CSF, dated 05/31/2018. However, there is no justification provided. I need to ask my manager about the pH range and I will correct that also.
7. It is not clear whether the test substance, DS6771, and test Substance Identification#405-18B11QUat, for the accelerated storage stability and corrosion characteristic studies(Guidelines 830.6317 and 830.6320) can represent the proposed product(Nugen 1ID 64(MRID#50597004).
   I included in the cover letter an explanation of the test substances DS6771 as the Nugen 1ID formulation. The DS6771 name identifies the product before we have a name for the EPA registration during the testing phase. The names of the test substance used in these studies is not the requested EPA primary brand name. The table below describes the formulation of the Test Substance.

Test Substance ID	Formulation Name	EPA Reg. No.	CSF followed
DS 6771 Lot # 6070-014	NUGEN 1ID-64	6836-*not yet assigned*	Basic

Lot # 6066-180 and 6066-181			

From: Daniels, Joseph
Sent: Friday, October 26, 2018 12:37 PM
To: 'Kathryn Rosario' <kathryn.rosario@lonza.com>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Good morning. Please see the attached efficacy review for 6836-GIA and -GIT. I will send along the acute toxicity and product chemistry reviews as soon as they are completed. Please let me know if you have any questions.

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Wednesday, August 8, 2018 4:31 PM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

have attached the data matrix for the 6836 GIA

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Wednesday, August 08, 2018 4:02 PM
To: Rosario Kathryn - Allendale
Cc: Miederhoff, Eric
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Good afternoon. Thank you for getting back to us on this. I know they will be using the same data, but can you please submit a data matrix for the secondary registration as well? Thanks!

Joe

From: Kathryn Rosario [mailto:kathryn.rosario@lonza.com]
Sent: Wednesday, August 8, 2018 3:22 PM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Hi Joe

In reference to our conference call on Monday, please see attached. The data matrix is revised as well. Let me know if you have any questions or need more information.

Regards,

[illegible]

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Thursday, August 02, 2018 10:51 AM
To: Walsh Jonathan - Allendale
Cc: Rosario Kathryn - Allendale; Miederhoff, Eric
Subject: RE: EPA Reg. No. 6836-GIT, GIA

That works. Please see below for the conference call information.

Conference number: 202-991-0477
Conference ID: 8647776

From: Jonathan Walsh [mailto:jonathan.walsh@lonza.com]
Sent: Thursday, August 2, 2018 10:46 AM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Kathryn Rosario <kathryn.rosario@lonza.com>; Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Could we meet at 1:00 on Monday?

Regards,
Jonathan

jonathan.walsh@lonza.com

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Thursday, August 02, 2018 10:41 AM
To: Walsh Jonathan - Allendale <jonathan.walsh@lonza.com>
Cc: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>; Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

We are free any time Monday afternoon before 4:30pm, and between 9:00-10:00am or 3:00-4:30pm on Tuesday.

Joe

From: Jonathan Walsh [mailto:jonathan.walsh@lonza.com]
Sent: Thursday, August 2, 2018 10:34 AM
To: Daniels, Joseph <Daniels.Joseph@epa.gov>
Cc: Kathryn Rosario <kathryn.rosario@lonza.com>; Miederhoff, Eric <Miederhoff.Eric@epa.gov>
Subject: RE: EPA Reg. No. 6836-GIT, GIA

Good Morning Joe,

Thanks for getting back so promptly. Please let me know what times work best for you on Monday or Tuesday next week.

Regards,
Jonathan

jonathan.walsh@lonza.com

From: Daniels, Joseph [mailto:Daniels.Joseph@epa.gov]
Sent: Thursday, August 02, 2018 7:22 AM
To: Walsh Jonathan - Allendale <jonathan.walsh@lonza.com>
Cc: Rosario Kathryn - Allendale <kathryn.rosario@lonza.com>; Miederhoff, Eric <miederhoff.eric@epa.gov>
Subject: EPA Reg. No. 6836-GIT, GIA

Good morning Jonathan. I just got your message from yesterday afternoon. Is there a time this afternoon or early next week that you two would be available for a conference call to discuss these two actions? We would be free between 2:00 and 3:00pm, and 4:00-4:30pm today, and are pretty open on Monday.

Joe Daniels
Environmental Protection Specialist
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 347-8669

This communication and its attachments, if any, may contain confidential and privileged information the use of which by other persons or entities than the intended recipient is prohibited. If you receive this transmission in error, please contact the sender immediately and delete the material from your system.

This communication and its attachments, if any, may contain confidential and privileged information the use of which by other persons or entities than the intended recipient is prohibited. If you receive this transmission in error, please contact the sender immediately and delete the material from your system.

This communication and its attachments, if any, may contain confidential and privileged information the use of which by other persons or entities than the intended recipient is prohibited. If you receive this transmission in error, please contact the sender immediately and delete the material from your system.

Tek, Vekalet

From: Tek, Vekalet
Sent: Tuesday, July 31, 2018 5:14 PM
To: Miederhoff, Eric (Miederhoff.Eric@epa.gov)
Cc: Hicks, Karen; Daniels, Joseph
Subject: FW: 6836-GIT_DP447579_Nugen Value CQ 64_TECHNICAL SCREEN PASSED
Attachments: 6836-GIT_DP448200_Nugen 1ID-32_Product Chemistry Technical Screen_Checklist.docx

Tracking:

Recipient	Delivery
Miederhoff, Eric (Miederhoff.Eric@epa.gov)	
Hicks, Karen	Delivered: 7/31/2018 5:14 PM
Daniels, Joseph	Delivered: 7/31/2018 5:14 PM
Miederhoff, Eric	Delivered: 7/31/2018 5:14 PM

Dear All,

Attached please find the product chemistry checklist-Technical Screen, for Product Chemistry Review. From a chemistry point of view, at this time, the technical screen for Reg.#6836-GIA _*DP448200*_Nugen 1ID 32 ___ PASSED however, additional questions to be answered or data to be addressed may remain.

NOTE TO PM:

1.The name of the product, **Nugen Value CQ 32**, on the proposed Basic CSF, dated 05/31/2018, does not match with the proposed label for this particular product.

2.The date(03/31/2018) on the updated Basic CSF and Data Matrix for **Nugen 1ID-64**, and Data Matrix for **Nugen 1ID-32** should be updated accordingly.

3.It should be clarified whether the proposed **Alternate CSF**, dated 05/31/2018, for **Nugen Value CQ 64** is valid? If so, please note that the product name on the CSF above is different from the proposed label.

4.The name of the product on the provided Transmittal Document should clearly be indicated for each submitted product.

Should you have any questions or concerns regarding the case above, please feel free to contact me.

Thank You!

Vekalet Tek

Vekalet Tek. Ph.D.
Chemist

1

Tek, Vekalet

10 Days Response for the Technical Screen required

From: Daniels, Joseph
Sent: Tuesday, July 31, 2018 1:15 PM
To: Tek, Vekalet
Subject: Reg. No. 6836-GIT, -GIA
Attachments: 6836-XXX Nugen 1ID-32 Data Matrix Agency rev2018-05-31.pdf; Nugen 1ID-64 Basic CSF 20180531.pdf; 6836-XXX Nugen 1ID-64 Data Matrix Agency rev2018-05-31.pdf

Good afternoon. Please see the attached revised CSF and Data matrices for both products. The primary brand name has changed, and I sent e-mails with labels and CSFs reflecting the new name last week. The names in OPPIN and on the documents in this e-mail are the correct names.

Joe Daniels
Environmental Protection Specialist
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 347-8669

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 8, 2018

Kathryn Rosario
Regulatory Assurance Specialist
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: PRIA Pre-Decisional Determination
Product Name: NUGEN HD-64, NUGEN HD-32
EPA Registration Number: 6836-GIT, 6836-GIA
Application Date: June 1, 2018
EPA Receipt Date: June 4, 2018
Decision Number: 541622, 541623

Dear Ms. Rosario:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified in the attached acute toxicity and efficacy reviews and commented label.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

(a) Applicant agrees to all of the terms associated with the attached acute toxicity and efficacy reviews and commented label and makes necessary changes; or
(b) Applicant does not agree to one or more of the terms of the attached acute toxicity and efficacy reviews and commented label by the Agency and requests additional time to resolve the difference(s); or
(c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will

have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the attached acute toxicity and efficacy reviews and commented label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

Sincerely,

E. Miederhoff

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: October 11, 2018

SUBJECT: NUGEN VALUE CQ 64
EPA Reg. No. 6836-GIT (Primary Product)
EPA Reg. No. 6836-GIA (Secondary Product)
DP Barcode: 447582
E-submission: 29741

FROM: Lorilyn M. Montford
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Kristen Willis, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: 10/25/2018

TO: Eric Miederhoff, PM 31/Joseph Daniels
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: LONZA Inc.
90 Boroline Road
Allendale, NJ 07401

FORMULATION FROM LABEL:

Reg. No. 6836-GIT

Active Ingredients:	% by wt.
Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate	3.03%
Inert ingredients	96.97%
Total	100.00%

Reg. No. 6836-GIA

Active Ingredients:	% by wt.
Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate	1.516%
Inert ingredients	98.484%
Total	100.00%

I. BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate/dilutable liquid

Submission type: New product registration

Currently registered efficacy claim(s): n/a
Requested action(s): Register two products as disinfectants (bactericide, virucide, and fungicide) for use on hard, non-porous surfaces in hospitals, medical facilities, residential, commercial (veterinary practices, farm premises), and institutional facilities.

Documents considered in this review:

- Letter from applicant to EPA dated June 1, 2018
- Data Matrix (EPA Form 8570-35), dated May 31, 2018
- 17 efficacy studies (MRIDs 505970-05 through 505970-21)
- Proposed label for EPA Reg. No. 6836-GIT, dated June 1, 2018
- Proposed label for EPA Reg. No. 6836-GIA, dated June 1, 2018 (e-sub: 29740)
- Confidential Statement of Formula (EPA form 8670-4), dated May 31, 2018

II. USE DIRECTIONS for EPA Reg. No. 6836-GIT

The product is designed for disinfecting hard, non-porous surfaces such as exteriors of appliances, bathrooms, floors, countertops, chairs, stoves, showers, refrigerators, walls, kennel runs, garbage cans, highchairs, toilets, urinals, and sinks. The label indicates that the product may be used on the following types of surfaces: Formica®, metal, glazed porcelain, glazed enameled surfaces, stainless steel, painted surfaces, vinyl and plastic upholstery, and woodwork.
The label states that the product is effective in the presence of a 5% organic soil load (5% serum).

Application:
For disinfection, remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 2 fl. oz. [1/4 cup] of the concentrate per gallon of water. Apply with a cloth, mop, sponge, or coarse sprayer, or by soaking. For sprayer applications, use a coarse spray device. Spray 6-8-inches from surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface for a minimum of 10 minutes. Rinse or wipe dry with a clean cloth or sponge or allow to air dry.

Rinse all surfaces that come in contact with food such as countertops, exterior surfaces of appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes or appliance interior surfaces as a disinfectant.

Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

Rinsing of floors is not necessary unless they are to be waxed or polished.

This product is not for use on medical device surfaces.

To Disinfect and Clean [throughout your home]:
Mix 2 fl. oz. [1/4 cup] per gallon of water. Let stand for a minimum of 10 minutes before wiping. For heavily soiled surfaces, a precleaning step is required.

For tough jobs:
Pour directly on sponge or soil. Let stand for a minimum of (contact time) before wiping. Rinse thoroughly with clean water.

For surfaces that may come in contact with food potable water rinse is required.

TOILET BOWLS: To clean, apply diluted solution around the bowl and up under the rim. Stubborn stains may require brushing.

To disinfect, first preclean to remove heavy soil, then [remove or expel over the inner trap the residual bowl water] or [empty bowl]. Pour in 3 fl. oz. of the diluted solution. [Swab the bowl completely using a scrub brush or mop] [Brush bowl completely], making sure to get under the rim. Let stand for 10 minutes [or overnight], then flush.

DISINFECTION OF BARBER / BEAUTY / SALON INSTRUMENTS AND TOOLS: Tools (such as combs, brushes, razors, scissors, and other shop tools) can be disinfected by immersing in a 2 fl. oz. [1/4 cup] per gallon solution for a contact time of at least 10 minutes. Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

FUNGICIDAL DIRECTIONS: NUGEN VALUE CQ 64 is an effective fungicide against *Trichophyton interdigitale* [the athlete's foot fungus] [a cause of ringworm] in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Follow disinfection directions.

MILDEWSTATIC DIRECTIONS:
[Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops.] Apply solution [2 fl. oz. [1/4 cup] per gallon of water] with a cloth, mop, sponge, or coarse sprayer, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application weekly or when growth reappears.

USE DIRECTIONS for EPA Reg. No. 6836-GIA
The product is designed for disinfecting hard, non-porous surfaces such as exteriors of appliances, bathrooms, floors, countertops, chairs, stoves, showers, refrigerators, walls, kennel runs, garbage cans, highchairs, toilets, urinals, and sinks. The label indicates that the product may be used on the following types of surfaces: Formica®, metal, glazed porcelain, glazed enameled surfaces, stainless steel, painted surfaces, vinyl and plastic upholstery, and woodwork.
The label states that the product is effective in the presence of a 5% organic soil load (5% serum).

Application:
For disinfection, remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 4 fl. oz. [1/2 cup] of the concentrate per gallon of water. Apply with a cloth, mop, sponge, or coarse sprayer, or by soaking. For sprayer applications, use a coarse spray device. Spray 6-8-inches from surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface for a minimum of 10 minutes. Rinse or wipe dry with a clean cloth or sponge or allow to air dry.

Rinse all surfaces that come in contact with food such as countertops, exterior surfaces of appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes or appliance interior surfaces as a disinfectant.

Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

Rinsing of floors is not necessary unless they are to be waxed or polished.

This product is not for use on medical device surfaces.

To Disinfect and Clean [throughout your home]:
Mix 4 fl. oz. [1/2 cup] per gallon of water. Let stand for a minimum of 10 minutes before wiping. For heavily soiled surfaces, a precleaning step is required.

For tough jobs:
Pour directly on sponge or soil. Let stand for a minimum of (contact time) before wiping. Rinse thoroughly with clean water.

For surfaces that may come in contact with food potable water rinse is required.

TOILET BOWLS: To clean, apply diluted solution around the bowl and up under the rim. Stubborn stains may require brushing.

To disinfect, first preclean to remove heavy soil, then [remove or expel over the inner trap the residual bowl water] or [empty bowl]. Pour in 3 fl. oz. of the diluted solution. [Swab the bowl completely using a scrub brush or mop] [Brush bowl completely], making sure to get under the rim. Let stand for 10 minutes [or overnight], then flush.

DISINFECTION OF BARBER / BEAUTY / SALON INSTRUMENTS AND TOOLS: Tools (such as combs, brushes, razors, scissors, and other shop tools) can be disinfected by immersing in a 4 fl. oz. [1/2 cup] per gallon solution for a contact time of at least 10 minutes. Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

FUNGICIDAL DIRECTIONS: NUGEN VALUE CQ 64 is an effective fungicide against *Trichophyton interdigitale* [the athlete's foot fungus] [a cause of ringworm] in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Follow disinfection directions.

MILDEWSTATIC DIRECTIONS:
[Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops.] Apply solution [4 fl. oz. [1/2 cup] per gallon of water] with a cloth, mop, sponge, or coarse sprayer, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application weekly or when growth reappears

III. AGENCY STANDARDS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product batches (at lowest certified limit – LCL), against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC15442). To support products labeled as "hospital disinfectants", killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level for the AOAC Germicidal Spray Method. To support products labeled as "hospital disinfectants" conducted utilizing the "Use-Dilution Method", killing on 57/60 carriers for *Staphylococcus aureus* and 54/60 carriers for *Pseudomonas aeruginosa* is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step.

Viricides: The effectiveness of viricides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of a disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Recommendations:

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. For disinfectant claims for toilet bowls, the contained bowl water (96 fl. oz of water) should be used to calculate the appropriate use-dilution for testing.

Fungicides

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method has been modified to conform with the appropriate elements to create the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different batches of product must be tested. Killing of the specific pathogenic fungi on all carriers is required.

IV. SUMMARY OF SUBMITTED DATA:

1. **MRID 505970-05, "AOAC Use-Dilution Method". Test Organism: *Enterobacter aerogenes* (ATCC 13048) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-180 and #6066-181. Study conducted at Microbac Laboratories, Inc. by Rana Rahmat. Study completion date – March 07, 2018. Project Number 163-887.**

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Two lots (Batch Nos. 6066-180 and 6066-181) of the product, DS6771, Nugen Value CQ 64 (6836-

GIT), were tested at the LCL using Microbac Protocol No. 163.2.01.23.18. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Nutrient Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were dried for 40±2 minutes at 36±1°C and 31-33% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33-35% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

2. **MRID 505970-06, "AOAC Use-Dilution Method". Test Organism: *Escherichia coli* (ATCC 11229) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-180 and #6066-181. Study conducted at Microbac Laboratories, Inc. by Rana Rahmat. Study completion date – March 07, 2018. Project Number 163-888.**

This study was conducted against *Escherichia coli* (ATCC 11229). Two lots (Batch Nos. 6066-180 and 6066-181) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.3.01.23.18. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Nutrient Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were dried for 40±2 minutes at 36±1°C and 31-33% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33-35% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

3. **MRID 505970-07, "AOAC Use-Dilution Method". Test Organism: *Klebsiella pneumoniae* (ATCC 4352) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots**

#6066-180 and #o066-181. Study conducted at Microbac Laboratories, Inc. by Rana Rahmat. Study completion date – March 07, 2018. Project Number 163-889.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two lots (Batch Nos. 6066-180 and 6066-181) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.4.01.23.18. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Nutrient Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were dried for 40±2 minutes at 36±1°C and 31-33% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33-35% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

4. **MRID 505970-08, "AOAC Use-Dilution Method". Test Organism: Methicillin-Resistant *Staphylococcus aureus* (ATCC 700699) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-180 and #6066-181. Study conducted at Microbac Laboratories, Inc. by Rana Rahmat. Study completion date – March 07, 2018. Project Number 163-894.**

This study was conducted against Methicillin-Resistant *Staphylococcus aureus* (ATCC 700699). Two lots (Batch Nos. 6066-180 and 6066-181) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.9.01.23.18. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Nutrient Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were dried for 40±2 minutes at 36±1°C and 31-33% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33-35% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin

to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, verification of antibiotic resistance, and confirmation of the challenge microorganisms.

5. **MRID 505970-09, "AOAC Use-Dilution Method". Test Organism: *Staphylococcus epidermidis* (ATCC 12228) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-180 and #6066-181. Study conducted at Microbac Laboratories, Inc. by Rana Rahmat. Study completion date – March 07, 2018. Project Number 163-893.**

This study was conducted against *Staphylococcus epidermidis* (ATCC 12228). Two lots (Batch Nos. 6066-180 and 6066-181) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.8.01.23.18. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Nutrient Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were dried for 40±2 minutes at 36±1°C and 31-33% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33-35% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

6. **MRID 505970-10, "AOAC Use-Dilution Method". Test Organism: *Serratia marcescens* (ATCC 14756) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-180 and #6066-181. Study conducted at Microbac Laboratories, Inc. by Rana Rahmat. Study completion date – March 07, 2018. Project Number 163-890.**

This study was conducted against *Serratia marcescens* (ATCC 14756). Two lots (Batch Nos. 6066-180 and 6066-181) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.5.01.23.18. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Nutrient Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper

portion was removed and pooled in a sterile vessel and mixed. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were dried for 40±2 minutes at 36±1°C and 31-33% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33-35% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

7. **MRID 505970-11, "AOAC Use-Dilution Method". Test Organism: *Shigella flexneri* (ATCC 12022) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-180 and #6066-181. Study conducted at Microbac Laboratories, Inc. by Rana Rahmat. Study completion date – March 07, 2018. Project Number 163-891.**

This study was conducted against *Shigella flexneri* (ATCC 12022). Two lots (Batch Nos. 6066-180 and 6066-181) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.6.01.23.18. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Nutrient Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were dried for 40±2 minutes at 36±1°C and 31-33% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33-35% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

8. **MRID 505970-12, "AOAC Use-Dilution Method". Test Organism: *Shigella sonnei* (ATCC 11060) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-180 and #6066-181. Study conducted at Microbac Laboratories, Inc. by Rana Rahmat. Study completion date – March 07, 2018. Project Number 163-892.**

This study was conducted against *Shigella sonnei* (ATCC 11060). Two lots (Batch Nos. 6066-180 and 6066-181) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.7.01.23.18. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and

briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Nutrient Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were dried for 40±2 minutes at 36±1°C and 31-33% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33-35% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

9. **MRID 505970-13, "AOAC Use-Dilution Method". Test Organism: *Streptococcus pyogenes* (ATCC 19615) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-180 and #6066-181. Study conducted at Microbac Laboratories, Inc. by Rana Rahmat. Study completion date – March 07, 2018. Project Number 163-886.**

This study was conducted against *Streptococcus pyogenes* (ATCC 19615). Two lots (Batch Nos. 6066-180 and 6066-181) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.1.01.23.18. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Brain Heart Infusion Broth, mixed and incubated under ~5% CO_2 in candle jars for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C under ~5% CO_2 in candle jars. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were dried for 40±2 minutes at 36±1°C and 31-33% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33-35% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C under ~5% CO_2 in candle jars. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

10. **MRID 505970-14, "AOAC Use-Dilution Method". Test Organism: *Pseudomonas aeruginosa* (ATCC 15442) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-107, #6066-108 and #6066-109. Study conducted at Microbac Laboratories, Inc. by Kathryn D. Dormstetter. Study completion date – January**

03, 2018. Project Number 163-881.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Batch Nos. 6066-107, 6066-108 and 6066-109) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.2.11.17.17. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Synthetic Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. For the purpose of achieving mean carrier counts within the specified range, dilution of the final test culture may be performed using Synthetic Broth and used within 30 minutes for carrier inoculation. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were covered and dried for 40±2 minutes at 36±1°C and 30-39% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 26-33% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

11. **MRID 505970-15, "AOAC Use-Dilution Method". Test Organism: *Salmonella enterica* (ATCC 10708) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-107, #6066-108 and #6066-109. Study conducted at Microbac Laboratories, Inc. by Kathryn D. Dormstetter. Study completion date – January 03, 2018. Project Number 163-882.**

This study was conducted against *Salmonella enterica* (ATCC 10708). Three lots (Batch Nos. 6066-107, 6066-108 and 6066-109) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.3.11.17.17. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Synthetic Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. For the purpose of achieving mean carrier counts within the specified range, dilution of the final test culture may be performed using Synthetic Broth and used within 30 minutes for carrier inoculation. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were covered and dried for 40±2 minutes at 36±1°C and 30-31% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier

was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 33% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

12. **MRID 505970-16, "AOAC Use-Dilution Method". Test Organism: *Staphylococcus aureus* (ATCC 6538) for DS6771, Nugen Value CQ 64 (6836-GIT), Lots #6066-107, #6066-108 and #6066-109. Study conducted at Microbac Laboratories, Inc. by Kathryn D. Dormstetter. Study completion date – January 03, 2018. Project Number 163-880.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (Batch Nos. 6066-107, 6066-108 and 6066-109) of the product, DS6771, Nugen Value CQ 64 (6836-GIT), were tested at the LCL using Microbac Protocol No. 163.1.11.17.17. A dilution of 1:64, defined as 1 part test substance + 63 parts diluent, was prepared using 250 ppm ± 2.9% AOAC hard water as diluent. A frozen cryovial of stock culture was defrosted at room temperature and briefly vortexed to mix. A 10 µL aliquot of the thawed stock culture was transferred to an initial 10 mL tube of Synthetic Broth growth medium, mixed and incubated for 24±2 hours at 36±1°C. Daily transfers were made for at least one but no more than five consecutive days. For the final subculture transfer, 10 µL of culture was transferred to tubes containing 10 mL of culture medium. The final test culture was incubated for 48-54 hours at 36±1°C. The test culture was vortex mixed (3-4 seconds) and allowed to sit 10 minutes at room temperature. The upper portion was removed and pooled in a sterile vessel and mixed. For the purpose of achieving mean carrier counts within the specified range, dilution of the final test culture may be performed using Synthetic Broth and used within 30 minutes for carrier inoculation. Heat-inactivated fetal bovine serum was added to the inoculum to achieve a 5% organic soil load. The test culture was directly applied to stainless steel penicylinders (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The carriers were covered and dried for 40±2 minutes at 36±1°C and 30-39% relative humidity. Inoculated carriers were used for testing within 2 hours after drying. Each contaminated and dried carrier was placed into a separate tube containing 10 mL of the test substance and the tube was swirled gently for 2-3 rotations. The carriers were exposed for 10 minutes at 20±1°C and 26-33% relative humidity. Each carrier was then transferred to Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralizer and shaken thoroughly. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, purity, and confirmation of the challenge microorganisms.

13. **MRID 505970-17, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces." Virus: Herpes simplex virus type 1 for product DS6771 (Batch 6066-180 and Batch 6066-181). Study conducted at Accuratus Lab Services by Matt Cantin, B.S. Study completion date – March 8, 2018. Project Number A24930.**

This study was conducted against the F(1) strain of Herpes simplex virus type 1 (ATCC VR-733) for product DS6771 (Batch 6066-180 and Batch 6066-181 at the LCL) using Accuratus Protocol No. LZ01012218.HSV1 (copy provided). Stock virus obtained from ATCC was prepared by collecting the supernatant culture fluid from 75-100% infected culture cells which were disrupted and cell debris removed by centrifugation at approximately 2000 RPM for 5 minutes at approximately 4°C. The supernatant was removed, aliquoted, and the high

titer stock virus was stored at ≤-70°C. On the day of use, an aliquot of stock virus (Accuratus Lot H85) was thawed, maintained at a refrigerated temperature until used in the assay; and contained 5% fetal bovine serum (FBS) as the organic soil load. The culture demonstrated cytopathic effects (CPE) typical of Herpes simplex virus on Vero cells. Indicator Vero cells originally obtained from ATCC (ATCC CCL-81) were propagated by Accuratus personnel, seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO_2. On the day of testing, the cells were observed as having proper cell integrity and confluency. Test medium used in this study was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated FBS, 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. Test substance was prepared and applied according to Sponsor's directions: 1:64 dilution defined as 1mL test substance plus 63 mL 250 ppm AOAC Synthetic Hard Water. The hard water was titrated at 244 ppm on the day of testing, and the diluted test substance was at exposure temperature prior to use. Films of virus were prepared by spreading 200 µL of virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. The virus films were dried at 20.0°C in relative humidity of 50% until visibly dry (20 minutes). On the day of testing, the stock virus utilized in the assay was titered by 10-fold serial dilution and assayed for infectivity to determine the starting titer of the virus. One dried virus film was individually exposed to a 2.00 mL aliquot of diluted test substance and held covered for 10 minutes exposure time at 20.0°C. Just prior to the end of exposure time, the plates were scraped with a cell scraper to re-suspend the contents. After exposure, the virus-test substance mixtures were immediately passed through a Sephadex column (Sephadex LH-20 gel) in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The indicator cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups. The cultures were incubated at 37.0°C in a humidified atmosphere of 6.0% CO_2. The cultures were scored periodically for 7 days for CPE, cytotoxicity and viability. Controls included those for virus stock titer confirmation, dried virus film recovery, cytotoxicity, neutralization and cell viability.

14. **MRID 505970-18, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces." Virus: Human Immunodeficiency virus type 1 for product DS6771 (Batch 6066-180 and Batch 6066-181). Study conducted at Accuratus Lab Services by Matt Cantin, B.S. Study completion date – March 27, 2018. Project Number A25066.**

This study was conducted against the HTLV-III_B strain of Human Immunodeficiency virus type 1 for product DS6771 (Batch 6066-180 and Batch 6066-181 at the LCL) using Accuratus Protocol No. LZ01012218.HIV (copy provided). Stock virus obtained from Advanced Biotechnologies, Inc. (Columbia, MD) was prepared by collecting the supernatant culture fluid from infected culture cells which were disrupted and cell debris removed by centrifugation at approximately 2200 RPM for 10 minutes at 4°C. The supernatant was removed, aliquoted, and the high titer stock virus was stored at ≤-70°C. On the day of use, an aliquot of stock virus (Accuratus Lot HIV-12) was thawed, maintained at a refrigerated temperature until used in the assay; and adjusted to contain 5% fetal bovine serum (FBS) as the organic soil load. The culture demonstrated cytopathic effects (CPE) typical of Human Immunodeficiency virus on MT-2 cells. Indicator MT-2 (human T-cell leukemia) cells obtained from NIH were maintained at 36-38°C in a humidified atmosphere of 5-7% CO_2. Test medium used in this study was RPMI-1640 supplemented with 15% (v/v) heat-inactivated FBS, 2.0 mM L-glutamine and 50 µg/mL gentamicin. Test substance was prepared and applied according to Sponsor's directions: 1:64 dilution defined as 1ml test substance plus 63 mL 250 ppm AOAC Synthetic Hard Water. The hard water was titrated at 249 ppm on the day of testing, and the diluted test substance was at exposure temperature prior to use. Films of virus were prepared by spreading 200 µL of virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. The virus films were dried at 22.0°C in relative humidity of 16.56% until visibly dry (20 minutes). On the day of testing, the stock virus used

in the assay was titered by 10-fold serial dilution and assayed for infectivity to determine the starting titer of the virus. For each lot of test substance one dried virus film was individually exposed to a 2.00 mL aliquot of diluted test substance and held covered for 10 minutes exposure time at 22.0°C Just prior to the end of exposure time, the plates were scraped with a cell scraper to re-suspend the contents. After exposure, the virus-test substance mixtures were immediately passed through a Sephadex column (Sephadex LH-20 gel) in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The indicator cells in multiwell culture dishes were inoculated in quadruplicate with 200 µL of the dilutions prepared from test and control groups. The cultures were incubated at 36-38°C in a humidified atmosphere of 6.1% CO_2. The cultures were scored periodically for 14 days for CPE, cytotoxicity and viability. Controls included those for virus stock titer confirmation, dried virus film recovery, cytotoxicity, neutralization and cell viability.

15. **MRID 505970-19, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces." Virus: Influenza A virus for product DS6771 (Batch 6066-180 and Batch 6066-181). Study conducted at Accuratus Lab Services by Matt Cantin, B.S. Study completion date – March 8, 2018. Project Number A24929.**

This study was conducted against the A/Hong Kong/8/68 strain of Influenza A virus (ATCC VR-544) for product DS6771 (Batch 6066-180 and Batch 6066-181 at the LCL) using Accuratus Protocol No. LZ01012218.FLUA (copy provided). Stock virus obtained from ATCC was prepared by collecting the supernatant culture fluid from 75-100% infected culture cells which were disrupted and cell debris removed by centrifugation at approximately 2000 RPM for 5 minutes at approximately 4°C. The supernatant was removed, aliquoted, and the high titer stock virus was stored at ≤-70°C. On the day of use, an aliquot of stock virus (Accuratus Lot NF6) was thawed, maintained at a refrigerated temperature until used in the assay; and adjusted to contain 5% fetal bovine serum (FBS) as the organic soil load. The culture demonstrated cytopathic effects (CPE) typical of Influenza virus on MDCK (canine kidney) cells. Indicator MDCK cells originally obtained from ATCC (ATCC CCL-34) were propagated by Accuratus personnel, seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO_2. On the day of testing, the cells were observed as having proper cell integrity and confluency. Test medium used in this study was Dulbecco's Minimum Essential Medium (D-MEM) supplemented with 2 µg/mL TPCK-trypsin, 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. Test substance was prepared and applied according to Sponsor's directions: 1:64 dilution defined as 1ml test substance plus 63 mL 250 ppm AOAC Synthetic Hard Water. The hard water was titrated at 248 ppm on the day of testing, and the diluted test substance was at exposure temperature prior to use. Films of virus were prepared by spreading 200 µL of virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. The virus films were dried at 20.0°C in relative humidity of 40% until visibly dry (20 minutes). On the day of testing, the stock virus used in the assay was titered by 10-fold serial dilution and assayed for infectivity to determine the starting titer of the virus. One dried virus film was individually exposed to a 2.00 mL aliquot of diluted test substance and held covered for 10 minutes exposure time at 20.0°C Just prior to the end of exposure time, the plates were scraped with a cell scraper to re-suspend the contents. After exposure, the virus-test substance mixtures were immediately passed through a Sephadex column (Sephadex LH-20 gel) in order to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution. The indicator cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups. The cultures were incubated at 37.0°C in a humidified atmosphere of 6.0% CO_2. The cultures were scored periodically for 7 days for CPE, cytotoxicity and viability. Controls included those for virus stock titer confirmation, dried virus film recovery, cytotoxicity, neutralization and cell viability.

16. **MRID 505970-20, "AOAC Use-Dilution Test." Test Organism: *Trichophyton***

***interdigitale* (ATCC 9533) for product DS6771 (Batch 6066-180 and Batch 6066-181). Study conducted at Microbac Laboratories by Rana Rahmat. Study completion date – March 27, 2018. Project Number 163-896.**

This study was conducted against *Trichophyton interdigitale* (ATCC 9533) for product DS6771 (Batch 6066-180 and Batch 6066-181 at the LCL) using Microbac Laboratories Protocol No. 163.11.01.23.18 (copy provided). The fungus was inoculated from stock cultures onto agar plates and incubated at 25-30°C for 10-15 days or until sporulation. When the cultures appeared to be mature, the mycelial mats were removed from the surface of at least 5 plates and macerated with sterile saline (SS) in a tissue grinder. The suspension was filtered through sterile glass wool to remove the hyphae and adjusted to contain a 5% heat-inactivated fetal bovine serum soil load. The density of the conidial suspensions were determined by standard plate count techniques. The plates were incubated tor 3-5 days at 25-30°C, then stored at 2-10°C for ≤4 weeks before use. Aliquots (20 mL) of the test culture were directly applied to the carriers (stainless steel penicylinders). The carriers remained in contact with the inocula (20 carriers per tube of 20 mL inocula) for 15±2 minutes at ambient temperature. The inoculum was. drained from the carriers with a pipette; each carrier was briefly tapped against the side of the tube to remove excess culture and placed on end vertically into sterile Petri dishes matted with filter paper. Carriers were dried at 36°C and 31-33% relative humidity for 40 minutes and were used for testing within 2 hours after drying. Test substance was prepared and applied according to Sponsor's directions (1:64 dilution defined as 1ml test substance plus 63 mL 250 ppm ± 2.9% AOAC Synthetic Hard Water) and was dispensed in 10mL aliquots into 25 x 100 mm or 25 x 150 mm sterile tubes (10 for each lot of test substance). The diluted test substance was at exposure temperature (21°C) prior to use, and was used within 3 hours of preparation. One contaminated carrier was added to each tube; the tube was swirled gently for 2-3 rotations (avoiding intense swirling or agitation); and the carrier remained in contact with the test substance for exposure time of 10 minutes. After the contact time, the carriers were removed, tapped gently against the interior sides of the tube to remove excess disinfectant, transferred to neutralizer (Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin) and shaken thoroughly. Transfers to recovery broth occurred within ±5 seconds of exposure time. All tubes were incubated at 25-30°C for up to ten days and observed for visible growth. Controls included those for sterility, neutralizer effectiveness, carrier count, viability, purity and challenge fungus confirmation.

17. **MRID 505970-21, "EPA Hard Surface Mildew-Fungistatic Test." Test organism: *Aspergillus niger* (ATCC 6275) for product DS6771 (Batch 6066-180 and Batch 6066-181). Study conducted at Accuratus Lab Services by Jamie Herzan, B.S. Study completion date – February 13, 2018. Project Number A24880.**

This study was conducted against *Aspergillus niger* for product DS6771 (Batch 6066-180 and Batch 6066-181 at the LCL) using Accuratus Laboratory Protocol No. LZ01012218.MSTAT (copy provided). The *Aspergillus niger* conidial suspension was prepared by inoculating a flask of Sabouraud Agar (Modified) (aka neopeptone agar) and incubating for 7 days at 29.0°C. Following incubation, sterile saline/Triton Solution (0.85% saline + 0.05% TritonX-100) and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and passed through sterile gauze to remove hyphal fragments. The actual viable titer (initial suspension) was determined by serial dilution and plating. The viable cell count was 5.2×10^7 CFU/mL. The suspension was added to a sterile tissue grinder and macerated to break up spore chains at the time of harvesting. The macerated conidial suspension was standardized to contain an approximate target of 5×10^6 conidia per mL by combining 1.00 mL of culture with 4.0 mL 0.85% saline. A 1.00 mL aliquot of this suspension was added to 20.0 mL of sterile Czapek's solution. Test substance was prepared and applied according to Sponsor's directions: 1:64 dilution defined as 1ml test substance plus 63 mL 250 ppm AOAC Synthetic Hard Water (actual titration 249 ppm). The hard water was used for testing within 3

hours of preparation, and the diluted test substance was at exposure temperature prior to use. For each lot of test substance, 10 sterile carriers (1x1 inch glazed ceramic tiles) were immersed in the diluted test substance and then placed in vertical or near-vertical position to permit excess liquid to drain, then dried in Petri dishes with lids ajar at 35-37°C and 38% relative humidity for 30 minutes. An atomizer was then used to spray the surface of each carrier with the *Aspergillus niger* conidia-Czapek suspension. Approximately 3 sprays were used to apply the test organism. The atomizer was periodically mixed to agitate the culture during inoculation. Carriers contained in Petri dishes were returned to an incubator at 36.2°C and 37% relative humidity for 45 minutes until visibly dry. Each carrier (sprayed side up) was placed onto an individual water agar plate. All plates were incubated for 7 days at 29.0°C in a minimum of 95% humidity. Carriers were then examined, including a magnified examination. Controls included those for purity and sterility.

V. Results

MRID Number	Organism	Batch No.	No. of Carriers Exhibiting Growth/ Total No. Tested	Carrier Population (Log_{10} CFU/ Carrier)
10 Minute Exposure Time (1:64[c]; 5% Soil Load; 250 ppm AOAC Synthetic Hard Water)				
505970-05	*Enterobacter aerogenes* (ATCC 13048)	Lot 6066-180 Lot 6066-181	0/10 0/10	5.10
505970-06	*Escherichia coli* (ATCC 11229)	Lot 6066-180 Lot 6066-181	0/10 0/10	5.40
505970-07	*Klebsiella pneumoniae* (ATCC 4352)	Lot 6066-180 Lot 6066-181	0/10 0/10	6.20
505970-08	*Staphylococcus aureus* Methicillin-Resistant (ATCC 700699)	Lot 6066-180 Lot 6066-181	0/10 0/10	6.10
505970-09	*Staphylococcus epidermidis* (ATCC 12228)	Lot 6066-180 Lot 6066-181	0/10 0/10	5.60
505970-10	*Serratia marcescens* (ATCC 14756)	Lot 6066-180 Lot 6066-181	0/10 0/10	6.60
505970-11	*Shigella flexneri* (ATCC 12022)	Lot 6066-180 Lot 6066-181	0/10 0/10	6.30
505970-12	*Shigella sonnei* (ATCC 11060)	Lot 6066-180 Lot 6066-181	0/10 0/10	6.60
505970-13	*Streptococcus pyogenes* (ATCC 19615)	Lot 6066-180 Lot 6066-181	0/10 0/10	5.30
MRID Number	**Organism**	**Batch No.**	**No. of Carriers Exhibiting Growth/ Total No. Tested**	**Average Carrier Population**

505970-14	*Pseudomonas aeruginosa* (ATCC 15442)	Lot 6066-107 Lot 6066-108 Lot 6066-109	5/60 6/60 5/60	1.8×10^{6} [a], 3.4×10^{6} [b] 3.0×10^{6} [a], 2.6×10^{6} [b] 2.9×10^{6} [a], 4.3×10^{6} [b]
505970-15	*Salmonella enterica* (ATCC 10708)	Lot 6066-107 Lot 6066-108 Lot 6066-109	1/60 1/60 1/60	2.3×10^{5} [a], 4.4×10^{5} [b] 3.1×10^{5} [a], 2.6×10^{5} [b] 2.5×10^{5} [a], 4.2×10^{5} [b]
505970-16	*Staphylococcus aureus* (ATCC 6538)	Lot 6066-107 Lot 6066-108 Lot 6066-109	3/60 1/60 2/60	6.2×10^{6} [a], 6.2×10^{6} [b] 1.6×10^{6} [a], 1.3×10^{6} [b] 3.9×10^{6} [a], 3.9×10^{6} [b]

[a] Pre-Test; [b] Post-Test; [c] 1-part test material and 63 parts diluent

10 Minute Exposure Time (1:64; 5% Soil Load; 250 ppm AOAC Synthetic Hard Water)*						
MRID Number	**Organism**	**Results**				
			Complete Inactivation		**Dried Virus Control**	**Viral Titer Reduction (Log_{10})**
505970-17	Herpes simplex virus type 1 (ATCC VR-733)	10^{-1} to 10^{-8} Dilutions	Batch 6066-180	Batch 6066-181	$10^{5.00}$ $TCID_{50}$/100 µL	≥4.50
		$TCID_{50}$/100 µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$		
505970-18	Human Immunodeficiency Virus type 1	10^{-1} to 10^{-7} Dilutions	Batch 6066-180	Batch 6066-181	$10^{5.00}$ $TCID_{50}$/200 µL	≥3.50
		$TCID_{50}$/200 µL	$\leq 10^{1.50}$	$\leq 10^{1.50}$		
505970-19	Influenza A virus (ATCC VR-544)	10^{-1} to 10^{-8} Dilutions	Batch 6066-180	Batch 6066-181	$10^{5.25}$ $TCID_{50}$/100 µL	≥5.75
		$TCID_{50}$/100 µL	$\leq 10^{0.50}$	$\leq 10^{0.50}$		

*Defined as 1 part test product and 63 parts diluent.

10 Minute Exposure Time (1:64; 5% Soil Load; 250 ppm AOAC Synthetic Hard Water)*				
MRID	**Organism**	**Average Carrier Count (Control Results) CFU per Carrier**	**Batch**	**Test Result**
505970-20	*Trichophyton interdigitale* (ATCC 9533)	1.1×10^{6}	6066-180	0/10 (No Growth)
			6066-181	0/10 (No Growth)

*Defined as 1 part test product and 63 parts diluent.

7 Day Exposure (1:64; No Soil Load; 250 ppm AOAC Synthetic Hard Water)*

MRID Number	Organism	Untreated Control Results (Day 7)	Batch	Test Result (Day 7)
505970-21	*Aspergillus niger* (ATCC 6275)	80-95% coverage	6066-180	0/10 (No Growth)
			6066-181	0/10 (No Growth)

*Defined as 1 part test product and 63 parts diluent

VI. STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50597005	Disinfectant, bactericidal	Hard, non-porous surfaces	Liquid, 1:64 dilution	10 minutes	5%	250 ppm AOAC Hard Water	• *Enterobacter aerogenes* (ATCC 13048)	**Yes**
50597006							• *Escherichia coli* (ATCC 11229)	
50597007							• *Klebsiella pneumoniae* (ATCC 4352)	
50597008							• Methicillin-Resistant *Staphylococcus aureus* (ATCC 700699)	
50597009							• *Staphylococcus epidermidis* (ATCC 12228)	
50597010							• *Serratia marcescens* (ATCC 14756)	
50597011							• *Shigella flexneri* (ATCC 12022)	
50597012							• *Shigella sonnei* (ATCC 11060)	
50597013							• *Streptococcus pyogenes* (ATCC 19615)	
50597014							• *Pseudomonas aeruginosa* (ATCC 15442)	
50597015							• *Salmonella enterica* (ATCC 10708)	
50597016							• *Staphylococcus aureus* (ATCC 6538)	
50597017	Disinfectant, virucidal	Hard, non-porous surfaces	Liquid, 1:64 dilution	10 minutes	5%	250 ppm AOAC Hard Water	• Herpes simplex virus type 1 F(1) strain (ATCC VR-733)	**Yes**
50597018							• Human Immunodeficiency virus type 1 HTLV-III_B strain	

50597019							• A/Hong Kong/8/68 strain of Influenza A virus (ATCC VR-544)	
50597020	Disinfectant, fungicidal	Hard, non-porous surfaces	Liquid, 1:64 dilution	10 minutes	5%	250 ppm AOAC Hard Water	• *Trichophyton interdigitale* (ATCC 9533)	**Yes**
50597021	Mildewstat	Hard, non-porous surfaces	Liquid, 1:64 dilution	7-day exposure	n/a	250 ppm AOAC Hard Water	• *Staphylococcus aureus* (ATCC 6538) • *Enterobacter aerogenes* (ATCC 13048)	**Yes**

Note: The efficacy testing for Reg. No. 6836-GIT was conducted at or below the LCL based on the use dilutions (4 fl oz/gallon) for Reg. No. 6836-GIA. As such, at this time, the strategy to cite the data generated for Reg. No. 6836-GIT to Reg. no. 6836-GIA is acceptable.

VII. LABEL COMMENTS

1.) The label claims that the product, NUGEN VALUE CQ 64, when diluted at 2 fl. oz [1/4 cup] per gallon of water is an effective disinfectant against the following bacteria on hard, non-porous surfaces in the presence of a 5% organic soil load for a 10-minute contact time:

Enterobacter aerogenes
Escherichia coli
Klebsiella pneumoniae
Methicillin-Resistant *Staphylococcus aureus*
Staphylococcus epidermidis
Serratia marcescens
Shigella flexneri
Shigella sonnei
Streptococcus pyogenes
Pseudomonas aeruginosa
Salmonella enterica
Staphylococcus aureus

These claims are acceptable as they are supported by the submitted data.

2.) The label claims that the product, NUGEN VALUE CQ 64, when diluted at 2 fl. oz [1/4 cup] per gallon of water is an effective disinfectant against the following viruses on hard, non-porous surfaces for a 10-minute contact time in the presence of a 5% organic soil load:

Herpes simplex Type 1 Virus (Herpes)
Influenza A virus (IInfluenza)

These claims are acceptable as they are supported by the submitted data providing that the label lists the same strains as in the submitted data.

3.) The label claims that following precleaning, the product, NUGEN VALUE CQ 64, when diluted at 2 fl. oz [1/4 cup] per gallon of water is an effective disinfectant against the following virus on hard, non-porous surfaces for a **5-minute** contact time:

HIV-1 (AIDS virus)

<u>This claim is not acceptable</u> as the submitted data were conducted with a 10-minute contact time.

4.) The label claims that the product, NUGEN VALUE CQ 64, when diluted at 2 fl. oz [1/4 cup] per gallon of water is an effective disinfectant against the following fungus on hard, non-porous surfaces for a 10-minute contact time:

Trichophyton interdigitale

This claim is acceptable as it is supported by the submitted data.

5.) The label claims that the product, NUGEN VALUE CQ 64, when diluted at 2 fl. oz [1/4 cup] per gallon of waterwill effectively control growth of the following fungus (for a 7-day period) when repeated weekly or when growth appears:

Aspergillus niger

This claim is acceptable as it is supported by the submitted data.

6.) Make the following changes to the proposed label:

a. On page 1, please qualify the terms, "Pseudomonacidal", and "Staphylocidal" with the specific relevant bacteria tested. As written these claims imply the product is effective against the entire genus of bacteria rather than the specific strains tested.

b. On page 3,
   - remove the claim "Sanitizes non-food contact hard, non-porous surfaces and floors." No data was submitted to support a non-food contact sanitization claim.
   - Qualify the claim "Disinfects [and/or] cleans [and/or] deodorizes on one [labor saving] step" with "when used according to the directions for disinfection."
   - Remove "heavy duty" from the claim "[Heavy Duty] Disinfecting [Multi-Purpose] Cleaner" as it implies heightened efficacy.

c. On page 7,
   - Specific strains and as appropriate ATCC designations should be listed
   - Remove *Aspergillus niger* from the list of fungi or make a separate section indicating the product is effective as a mildewstat against *Aspergillus niger*.

d. On pages 8-10, clarify the dilution instructions to indicate 2 fl. oz. should be added to a total volume of 1 gallon to reflect the tested concentration.

e. On page 8, a claim for a 10-minute contact time for HIV-1 (AIDS virus) may be added

Note to PM: Efficacy did not conduct a label review for Reg. No. 6836-GIA, however as the data submitted in support of the Primary product, NUGEN VALUE CQ 64 (6836-GIT), is also supportive of the Secondary product, NUGEN VALUE CQ 32 (6836-GIA,. The same label claims apply to both proposed products.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

10/17/2018

SUBJECT: Acute Toxicity Review for *Nugen Value CQ 64*, EPA Reg. No. **6836-GIT** (primary) and *Nugen Value CQ 32*, EPA Reg. No. **6836-GIA** (secondary), DP 447581

FROM: Boris S. Yurchak, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Jenny Tao, Team Leader (Acute Toxicology) 11/7/2018
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Eric Miederhoff/Joseph Daniels
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: Lonza, Inc			
Action Code A540	Decision No.: 541622	Submission No.: 1020662	E-Sub No.: 29741
MRID No(s).: 43649103 , 43649104, 43649105			

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
069208	148788-55-0	Didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate, a.k.a. DDACB	3.03
		Other Ingredients	96.97
		Total	100.00

I. BACKGROUND

The Registrant, Lonza, Inc, has submitted acute toxicity studies/data to support the registration of their products: *Nugen Value CQ 64*, EPA Reg. No. 6836-GIT (primary) and *Nugen Value CQ 32*, EPA Reg. No. 6836-GIA (secondary). The proposed products are multi-purpose, germicidal detergents aimed to sanitize non-food contact hard, non-porous surfaces and floors.

II. RELEVANT DOCUMENTS

The data package included:

1. Cover letters from the Registrant to EPA, dated 6/1/2018.
2. Application for pesticide registration, Form 8570-1.
3. Proposed Basic CSF, dated 5/31/2018.
4. Revised Data matrix, dated 5/31/2018 (email attachment to the Agency, 08/08/2018).
5. Proposed Label, undated.

III. FINDINGS/RECOMMENDATIONS

3.1. In the revised Data Matrix, the registrant cites acute oral toxicity, dermal irritation, and skin sensitization studies conducted for EPA Reg. No. 6836-236, a manufacturing-use product that contains 50% same active ingredient, didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate. Therefore, the Agency will prepare the acute toxicity review based on the cited product and the studies. The cited product and the studies were assessed in the EPA Memorandum "Didecyl dimethyl ammonium carbonate/bicarbonate (DDACB; Bardac 22C50): Toxicology Hazard Characterization for the Human Health Assessment Scoping Document in Support of Registration Review of Didecyl Dimethyl Ammonium Carbonate/Bicarbonate.", EPA, May 1, 2012.

3.2. Based on the EPA Document provided above, the acute toxicity profile of *Nugen Value CQ 64*, EPA Reg. No. 6836-GIT and *Nugen Value CQ 32*, EPA Reg. No. 6836-GIA (secondary) is currently:

GRN	Study	MRID	Toxicity Category	Status
870.1100	Acute Oral Toxicity	43649103	II	Cited
870.1200	Acute Dermal Toxicity	N/A	I	Waived*/Cited
870.1300	Acute Inhalation Toxicity	N/A	I	Waived*/Cited
870.2400	Primary Eye Irritation	N/A	I	Waived*/Cited
870.2500	Primary Skin Irritation	43649104	I	Cited
870.2600	Dermal Sensitization	43649105	Non-sensitizer	Cited

* Data waivers for acute toxicity studies granted based upon the corrosive nature of the DDA carbonate/bicarbonate active ingredients. Consequently, the acute dermal, acute inhalation, and primary eye irritation studies are assigned Toxicity Category I for labeling purposes.

CONCLUSION:

The acute toxicity studies/data provided for the products EPA Reg. No. 6836-GIT and EPA Reg. No. 6836-GIA have been deemed adequate for regulatory purpose only to support their registrations.

IV. PRODUCT LABELING

1. Signal Word: **DANGER-POISON, Skull & Crossbones required**

2. The statement, **"Keep Out of Reach of Children (KOROC)"**, is required. It should appear immediately below the front-panel signal word "DANGER".

3. The Agency's *Label Review Manual* (https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf) indicates the following human-hazard precautionary statements:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

DANGER-POISON. Corrosive. Causes irreversible eye damage and skin burns. Fatal if absorbed through skin or inhaled. May be fatal if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear protective eyewear such as goggles, face shield, or safety glasses. Wear coveralls worn over long-sleeved shirt and long pants, socks and chemical-resistant boots, and waterproof gloves (Barrier Laminate, or Butyl Rubber, or Nitrile Rubber, or Neoprene Rubber, or Natural Rubber, or Poly-ethylene, or Polyvinyl Chloride (PVC), or Viton, selection Category A). Wear a minimum NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; or a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; or a NIOSH-approved powered air purifying respirator with HE filters. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact 1-800-222-1222, the poison control center, for emergency medical treatment information.

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

This product meets the Agency requirements for *Restricted-Use Classification* based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

Based upon data placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for *Child-Resistant Packaging* (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that the Product Manager assign this product Restricted-Use classification; if not, the registrant should place this product in CRP.

Note to PM/CRM/Registrant:

The proposed label should contain a Note to Physician which addresses the Toxicity Category I for primary eye and dermal irritation. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Sheahin, Marc

From: Kathryn Rosario <kathryn.rosario@lonza.com>
Sent: Thursday, June 14, 2018 11:13 AM
To: Sheahin, Marc
Subject: RE: Application for EPA Reg.# 6836-GIT - Confidential
Attachments: Nugen Value CQ 64 Basic CSF 20180531.pdf

Hi Marc,

I have attached revised CSF. Let me know if you need any additional information.

Best Regards,

mailto:kathryn.rosario@lonza.com
http://www.lonza.com

From: Sheahin, Marc [mailto:Sheahin.Marc@epa.gov]
Sent: Friday, June 08, 2018 1:27 PM
To: Rosario Kathryn - Allendale
Subject: Application for EPA Reg.# 6836-GIT - Confidential

Dear Ms. Rosario,

My name is Marc Sheahin and I am a contractor with the EPA. I am contacting you in regards to your submission in support of Nugen Value CQ 64 (EPA Reg. Number: 6836-GIT). We have found a deficiency with the submission that will need to be addressed:

1. Can you add a product registration number on the CSF? 6836-XX.

Please send all necessary documents to this e-mail address by 06/20. After that date, please send directly to the PM. If you have any questions, please do not hesitate to contact me.

Thanks,
Marc Sheahin

Contractor, US EPA
2777 S. Crystal Drive, S-4811
Arlington, VA 22202

A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	✓		
830.1600	Description of materials used to produce the product	✓		
830.1650	Description of formulation process	✓		
830.1670	Discussion on the formation of impurities	✓		
830.1700	Preliminary analysis	✓		
830.1750	Certified limits (158.345)	✓		
830.1800	Enforcement analytical method	✓		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	✓		
830.6303	Physical State	✓		
830.6304	Odor	✓		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓		
830.6315	Flammability	✓		
830.6316	Explodability	✓		
830.6317	Storage stability*	✓		
830.6319	Miscibility	✓		
830.6320	Corrosion Characteristics*	✓		
830.6321	Dielectric Breakdown Voltage	✓		
830.7000	pH	✓		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	✓		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	✓		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required *May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:

1) supply the product specific acute toxicity 6 pack data (listed below),

2) provide a bridging rationale document or waiver request or,

3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		✓		
830.1200	Acute Dermal (LD50)		✓		
830.1300	Acute Inhalation (LC50)			✓	
830.2400	Acute Eye Irritation		✓		
830.2500	Acute Dermal Irritation			✓	
830.2600	Dermal Sensitization		✓		

31

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 6/4/18

Experts In-Processing Signature: MT Date 6/6/18 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes _____ Date _____

EPA Reg. Number: 6836-GIT	EPA Receipt Date: 6/4/18

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) No inerts to review.	yes	no			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes X	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			
10	**<u>Required Data</u> and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

Documentation: Pass

-CSF revised, see email.
-All required forms are complete.

Inerts: N/A

-Technical and water only, no inerts to review.

11-3: Pass

-MRID 505970

Status: Pass

-ms 06/14/18

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 5, 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-541622
EPA File Symbol or Registration Number: 6836-GIT
Product Name: Nugen Value CQ 64
EPA Receipt Date: 04-Jun-2018
EPA Company Number: 6836
Company Name: LONZA INC

MS. KATHRYN ROSARIO
LONZA INC
90 BOROLINE ROAD
ALLENDALE , NJ 07401-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Pay.gov

Receipt

Your payment is complete

Pay.gov Tracking ID: 26A23BF5
Agency Tracking ID: 75499722753
Form Name: Pesticide Registration Improvement Act - Prepayment
Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card
Payment Amount: $5,107.00
Transaction Date: 06/01/2018 02:34:21 PM EDT
Payment Date: 06/01/2018
Registration Number: 6836-not yet assigned
Company Name: Lonza Inc.
Company Number: 6836
Action Code: A540

Account Information

Cardholder Name: Commerical Regulatory Lonza Inc.
Card Type: Visa
Card Number: **********0224

Email Confirmation Receipt

Confirmation Receipts have been emailed to:
kathryn.rosario@lonza.com

Pay.gov

Receipt

Your payment is complete

Pay.gov Tracking ID: 26A23BGI
Agency Tracking ID: 75499727777
Form Name: Pesticide Registration Improvement Act - Prepayment
Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card
Payment Amount: $2,554.00
Transaction Date: 06/01/2018 02:39:35 PM EDT
Payment Date: 06/01/2018
Registration Number: 6836-not yet assigned
Company Name: Lonza Inc.
Company Number: 6836
Action Code: A540.1

Account Information

Cardholder Name: Commercial Regulatory Lonza Inc.
Card Type: Visa
Card Number: **********0224

Email Confirmation Receipt

Confirmation Receipts have been emailed to:
kathryn.rosario@lonza.com

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number	EPA Registration Number/ File Symbol
LONZA, Inc. – 90 Boroline Road, Allendale, NJ 07401 (201)316-9327	**6836-*Not Yet Assigned***
Active Ingredient(s) and/or representative test compound(s) a) Didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate (EPA A.I.# 69208)	Date **June 1, 2018**
General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) *Food-handling/storage establishments, premises and equipment; Commercial, institutional and industrial premises and equipment; Residential and public access premises; Medical premises and equipment*	Product Name **NUGEN VALUE CQ 64**

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product, and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
[signature]	**June 1, 2018**	**Kathryn Rosario, Regulatory Assurance Specialist**

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **June 19, 2018**	EPA Reg. No./File Symbol: **6836-236**	Page 1 of 4
Applicant's/Registrant's Name & Address: **LONZA, Inc., 90 Boroline Road, Allendale NJ 07401**	Product: **Bardac 22C50**	

Ingredient(s): **Didecyl dimethyl ammonium carbonate (CAS #148788-55-0) and Didecyl dimethyl ammonium bicarbonate (CAS #148812-65-1)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	43649101 46329801	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
830.1600	Description of the Materials Used to Produce the Product	43649101 46329801	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
830.1650	Description of the Manufacturing Process	43649101 45524301 46329801	Lonza Inc. (#6836) Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN OWN	
830.1670	Discussion of Formation of Impurities	43649101 46329801	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
830.1700/62-1	Preliminary Analysis	43685701 46329802	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
830.1750	Certified Limits	43649102	Lonza Inc. (#6836)	OWN	
830.1800	Enforcement Analytical Method	43685701	Lonza Inc. (#6836)	OWN	
830.6302	Color	43685701 45524303	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
830.6303	Physical State	43685701 45524303	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
830.6304	Odor	43685701 45524303	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
830.6313	Stability	Not Applicable			Footnote 1
830.6314	Oxidation/Reduction: Chemical Compatibility	Not Applicable			Footnote 1
830.6315	Flammability	43685701 45524303	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
830.6316	Explodability	Not Applicable			Footnote 2
830.6317	Storage Stability (Accelerated) Storage Stability (One-Year) Storage Stability (One-Year)	43685701 45524302 45524303	Lonza Inc. (#6836) Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN OWN	
830.6319	Miscibility	Not Applicable			Footnote 3
830.6320	Corrosion Characteristics	43685701 45524303	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN	
830.6321	Dielectric Breakdown Voltage	Not Applicable			Footnote 4
830.7000	pH	43685701 45524303	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	

Signature	Name and Title:	Date
	Kathryn Rosario, Regulatory Assurance Specialist	June 19, 2018

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **June 19, 2018**

EPA Reg. No./File Symbol: **6836-236**

Applicant's/Registrant's Name & Address:
LONZA, Inc., 90 Boroline Road, Allendale NJ 07401

Product:
Bardac 22C50

Ingredient(s): **Didecyl dimethyl ammonium carbonate (CAS #148788-55-0) and Didecyl dimethyl ammonium bicarbonate (CAS #148812-65-1)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7100	Viscosity	43685701 45524303	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN	
830.7200	Melting Point	Not Applicable			Footnote 1
830.7220	Boiling Point	Not Applicable			Footnote 1
830.7300	Density/Relative Density/Bulk Density	43685701 45524303	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
830.7370	Dissociation Constant	Not Applicable			Footnote 5
830.7520	Particle Size, Fiber Length and Diameter Distribution	Not Applicable			Footnote 6
830.7550/7560/7570	Partition Coefficient	Not Applicable			Footnote 7
830.7860	Solubility (Generator column method)	Not Applicable			Footnote 1
830.7950	Vapor Pressure	Not Applicable			Footnote 1
161-1	Hydrolysis	41175801	Lonza Inc. (#6836)	OWN	Footnote 8
163-1	Special Leaching Study	45524305	Lonza Inc. (#6836)	OWN	
850.2100/ 71-1	Acute Avian Oral Toxicity: Bobwhite Quail or Mallard Duck	43685702	Lonza Inc. (#6836)	OWN	
850.2200/ 71-2	Avian Subacute Dietary Toxicity: Bobwhite Quail /Mallard Duck	43649106 43707101	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	Footnote 8
850.1075/ 72-1	Freshwater Fish Toxicity: Bluegill Sunfish	43649107	Lonza Inc. (#6836)	OWN	
850.1075/ 72-1	Freshwater Fish Toxicity: Rainbow Trout	43649108	Lonza Inc. (#6836)	OWN	
850.1010/ 72-2	Acute Toxicity to Freshwater Invertebrates	43649109	Lonza Inc. (#6836)	OWN	
850.1075/ 72-3	Acute Toxicity- Estuarine/Marine Organisms Sheepshead Minnow	43649110	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN	
850.1025/ 72-3	Acute Toxicity- Estuarine/Marine Organisms Oyster	43649112 44696502	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
850.1035/ 72-3	Acute Toxicity - Estuarine/Marine Organisms. Mysid Shrimp	43649111 44696501	Lonza Inc. (#6836) Lonza Inc. (#6836)	OWN OWN	
870.1100/81-1	Acute Oral Toxicity	43649103	Lonza Inc. (#6836)	OWN	
870.1200/81-2	Acute Dermal Toxicity	Waived			
870.1300/81-3	Acute Inhalation Toxicity	Waived			
870.2400/81-4	Acute Eye Irritation	Waived			

Signature	Name and Title:	Date
	Kathryn Rosario, Regulatory Assurance Specialist	June 19, 2018

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: June 19, 2018	EPA Reg. No./File Symbol: 6836-236	Page 3 of 4
Applicant's/Registrant's Name & Address: **LONZA, Inc., 90 Boroline Road, Allendale NJ 07401**	Product **Bardac 22C50**	

Ingredient(s): **Didecyl dimethyl ammonium carbonate (CAS #148788-55-0) and Didecyl dimethyl ammonium bicarbonate (CAS #148812-65-1)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2500/81-5	Acute Dermal Irritation	43649104	Lonza Inc. (#6836)	OWN	
870.2600/81-6	Skin Sensitization	43649105	Lonza Inc. (#6836)	OWN	
870.3100/82-1(a)	Subchronic Rodent Oral Toxicity 90-Day	40966302	Lonza Inc. (#6836)	OWN	Footnote 8
870.3150/82-1(b)	Subchronic Nonrodent Oral Toxicity 90-Day	40262901	Lonza Inc. (#6836)	OWN	Footnote 8
870.3250/ 82-3	Subchronic Dermal Toxicity, 90 Days	41305901	Lonza Inc. (#6836)	OWN	Footnote 8
870.4100/83-1(b)	Chronic Feeding Toxicity – Dog	41970401	Lonza Inc. (#6836)	OWN	Footnote 8
870.4200/83-2(a)	Oncogenicity – Rat	41965101	Lonza Inc. (#6836)	OWN	Footnote 8
870.4200/83-2(b)	Oncogenicity - Mice	41802301	Lonza Inc. (#6836)	OWN	Footnote 8
870.3700/83-3(a)	Developmental Toxicity – Rat	41886701	Lonza Inc. (#6836)	OWN	Footnote 8
870.3700/83-3(b)	Developmental Toxicity – Rabbit	41018701	Lonza Inc. (#6836)	OWN	Footnote 8
870.3800/83-4	Reproduction and Fertility Effects – Two Generation	41804501	Lonza Inc. (#6836)	OWN	Footnote 8
870.5300/84-2	*in Vitro* Mammalian Cell Gene Mutation – CHO/HGPRT Forward Mutation Assay	40895202	Lonza Inc. (#6836)	OWN	Footnote 8
870.5375/84-2	*in Vitro* Mammalian Chromosome Aberration - CHO	41252601	Lonza Inc. (#6836)	OWN	Footnote 8
870.5550/84-4	Bacterial DNA Damage/Repair – UDS	40895201	Lonza Inc. (#6836)	OWN	Footnote 8
870.7485/85-1	Metabolism and Pharmacokinetics	41385101	Lonza Inc. (#6836)	OWN	Footnote 8
875.1100	Applicator Exposure – Dermal	45524304	Lonza Inc. (#6836)	OWN	Footnote 9
875.1300	Applicator Exposure – Inhalation	45524304	Lonza Inc. (#6836)	OWN	Footnote 9

Signature	Name and Title:	Date
	Kathryn Rosario, Regulatory Assurance Specialist	June 19, 2018

EPA Form 8570-1 (Electronic and Paper versions) - Available Software Packages

Agency Internal Use Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date **June 19, 2018**	EPA Reg. No./File Symbol **6836-236**	Page 4 of 4
Applicant's/Registrant's Name & Address: **LONZA, Inc., 90 Boroline Road, Allendale NJ 07401**	Product: **Bardac 22C50**	

Ingredient(s): **Didecyl dimethyl ammonium carbonate (CAS #148788-55-0) and Didecyl dimethyl ammonium bicarbonate (CAS #148812-65-1)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

FOOTNOTES:

1. The active ingredients are manufactured using an integrated process and are never isolated in their pure form. Consequently, a determination of the melting/boiling point, solubility, vapor pressure and stability of the active ingredients is not feasible nor would any useful information be provided. However, based on studies done with closely related quaternary ammonium compounds, such as DDAC, show these active ingredients are soluble in water and have a negligible vapor pressure.
2. Not potentially explosive.
3. Not to be diluted with petroleum solvents.
4. Not for use around electric equipment.
5. Quaternary ammonium compounds ionize completely under use-conditions.
6. Not water insoluble or fibrous.
7. Not organic and non-polar.
8. These studies were conducted with the "model" straight-chain Quat, DDAC (A.I.# 69149). In accordance with the cluster approach adopted by the Agency these studies satisfy the corresponding data requirements for Didecyl dimethyl ammonium carbonate.
9. Conducted with DDAC (counter ion, chloride for DDAC, carbonate for Bardac 22C50 AIs); dermal and inhalation exposures should be identical.

Signature	Name and Title:	Date
	Kathryn Rosario, Regulatory Assurance Specialist	June 19, 2018

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

PRODUCT SPECIFIC DATA MATRIX

Date: **November 19, 2018**	EPA Reg. No./File Symbol **6836-XXX**	Page 1 of 3
Applicant's/Registrant's Name & Address: **Lonza Inc.** **412 Mount Kemble Avenue, Suite 200S** **Morristown, NJ 07960**	Product: **NuGEN 1ID-64**	

Ingredient(s): **a) Didecyl dimethyl ammonium carbonate (EPA A.I.# 69208); and**
b) Didecyl dimethyl ammonium bicarbonate (EPA A.I.# 69208)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY					
830.1550	Product Identity and Composition	50597001	LONZA (Co. #6836)	OWN	
830.1600	Description of the Materials Used to Produce the Product	50597001	LONZA (Co. #6836)	OWN	
830.1620	Description of the Production Process	50597001			
830.1650	Description of the Formulation Process	50597001	LONZA (Co. #6836)	OWN	
830.1670	Discussion of Formation of Impurities	50597001	LONZA (Co. #6836)	OWN	
830.1700	Preliminary Analysis	50597001	LONZA (Co. #6836)	OWN	
830.1750	Certified Limits	50597001	LONZA (Co. #6836)	OWN	
830.1800	Enforcement Analytical Method	49445602	LONZA (Co. #6836)	OWN	
830.1900	Submission of Sample	50597001	LONZA (Co. #6836)	OWN	
830.6302	Color	50597003	LONZA (Co. #6836)	OWN	
830.6303	Physical State	50597002	LONZA (Co. #6836)	OWN	
830.6304	Odor	50597003	LONZA (Co. #6836)	OWN	
830.7200	Melting Point	50597003	LONZA (Co. #6836)	OWN	
830.7220	Boiling Point	50597003	LONZA (Co. #6836)	OWN	
830.7300	Density/Relative Density/Bulk Density	50597002	LONZA (Co. #6836)	OWN	
830.7840/7860	Solubility (Column elution/shake flask)	50597003	LONZA (Co. #6836)	OWN	
830.7950	Vapor Pressure	50597003	LONZA (Co. #6836)	OWN	
830.7370	Dissociation Constant	50597003	LONZA (Co. #6836)	OWN	
830.7550/7560/7570	Partition Coefficient	50597003	LONZA (Co. #6836)	OWN	
830.7000	pH	50597002	LONZA (Co. #6836)	OWN	
830.7050	UV/Visible Absorption	50597003	LONZA (Co. #6836)	OWN	
830.6313	Stability	50597003	LONZA (Co. #6836)	OWN	
830.6314	Oxidation/Reduction: Chemical Compatibility	50597003	LONZA (Co. #6836)	OWN	
830.6315	Flammability	50597002	LONZA (Co. #6836)	OWN	
830.6316	Explodability	50597003	LONZA (Co. #6836)	OWN	
830.6317	Storage Stability	50597004	LONZA (Co. #6836)	OWN	
830.7100	Viscosity	50597002	LONZA (Co. #6836)	OWN	

Signature	Name and Title: **Kathryn Rosario, Regulatory Assurance Specialist**	Date: **11/19/2018**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

PRODUCT SPECIFIC DATA MATRIX

Date: **November 19, 2018**	EPA Reg. No./File Symbol **6836-XXX**	Page 2 of 3
Applicant's/Registrant's Name & Address: **Lonza Inc.** **412 Mount Kemble Avenue, Suite 200S** **Morristown, NJ 07960**	Product: **NuGEN 1ID-64**	

Ingredient(s): **a) Didecyl dimethyl ammonium carbonate (EPA A.I.# 69208); and**
b) Didecyl dimethyl ammonium bicarbonate (EPA A.I.# 69208)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility	50597003	LONZA (Co. #6836)	OWN	
830.6320	Corrosion Characteristics	50597004	LONZA (Co. #6836)	OWN	
830.6321	Dielectric Breakdown Voltage	50597003	LONZA (Co. #6836)	OWN	
ACUTE TOXICITY					
870.1100/81-1	Acute Oral Toxicity	43649103	LONZA (Co. #6836)	OWN	
870.1200	Acute Dermal Toxicity	43649103	LONZA (Co. #6836)	OWN	
870.1300	Acute Inhalation Toxicity	47426203	LONZA (Co. #6836)	OWN	
870.2500/81-5	Acute Dermal Irritation	43649104	LONZA (Co. #6836)	OWN	
870.2600/81-6	Skin Sensitization	43649105	LONZA (Co. #6836)	OWN	
870.2400	Acute Eye Irritation	NA		NON-COMPENSABLE	Footnote 1
EFFICACY					
	Bactericidal Label Claims				
810.2200	Enterobacter aerogenes (ATCC 13048)	50597005	LONZA (Co. #6836)	OWN	
810.2200	Escherichia coli (ATCC 11229)	50597006	LONZA (Co. #6836)	OWN	
810.2200	Klebsiella pneumoniae (ATCC 4352)	50597007	LONZA (Co. #6836)	OWN	
810.2200	Methicillin-Resistant Staphylococcus aureus (ATCC 700699)	50597008	LONZA (Co. #6836)	OWN	
810.2200	Staphylococcus epidermis (ATCC 12228)	50597009	LONZA (Co. #6836)	OWN	
810.2200	Serratia marcescens (ATCC 14756)	50597010	LONZA (Co. #6836)	OWN	
810.2200	Shigella flexneri (ATCC 12022)	50597011	LONZA (Co. #6836)	OWN	
810.2200	Shigella sonnei (ATCC 11060)	50597012	LONZA (Co. #6836)	OWN	
810.2200	Streptococcus pyogenes (ATCC 19615)	50597013	LONZA (Co. #6836)	OWN	
810.2200	Pseudomonas aeruginosa, ATCC 15442	50597014	LONZA (Co. #6836)	OWN	
810.2200	Salmonella enterica, ATCC 10708	50597015	LONZA (Co. #6836)	OWN	
810.2200	Staphylococcus aureus, ATCC 6538	50597016	LONZA (Co. #6836)	OWN	

Signature	Name and Title: **Kathryn Rosario, Regulatory Assurance Specialist**	Date: **11/19/2018**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

PRODUCT SPECIFIC DATA MATRIX

Date: **November 19, 2018**	EPA Reg. No./File Symbol **6836-XXX**	Page 3 of 3
Applicant's/Registrant's Name & Address: **Lonza Inc.** **412 Mount Kemble Avenue, Suite 200S** **Morristown, NJ 07960**	Product: **NuGEN 1ID-64**	
Ingredient(s): **a) Didecyl dimethyl ammonium carbonate (EPA A.I.# 69208); and** **b) Didecyl dimethyl ammonium bicarbonate (EPA A.I.# 69208)**		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Virucidal Label Claims				
810.2200	Herpes Simplex Virus Type I (ATCC VR-733, Strain F(1)	50597017	LONZA (Co. #6836)	OWN	
810.2200	Human Immunodeficiency Virus type 1, Strain HTLV-IIIB	50597018	LONZA (Co. #6836)	OWN	
810.2200	Influenza A Virus (ATCC VR-544) (strain A/Hong Kong/8/68)	50597019	LONZA (Co. #6836)	OWN	
	Fungicidal Label Claims				
810.2200	Trichophyton interdigitale (ATCC 9533)	50597020	LONZA (Co. #6836)	OWN	
40 CFR 161, G, 93-30	Aspergillus niger (ATCC 6275)	50597021	LONZA (Co. #6836)	OWN	

FOOTNOTES:

1 Per "EPA Batching of End-Use Products for Meeting Acute Toxicological Data Requirements of Reregistration," under DDAC DCI Case #3003, the data/information used by the agency to support this default classification is considered non-compensable.

Signature	Name and Title **Kathryn Rosario, Regulatory Assurance Specialist**	Date **11/19/2018**

Lonza

Mr. Eric Miederhoff, PM-31
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Lonza Inc.
90 Boroline Road
Allendale, NJ
07401

Kathryn Rosario
Regulatory Assurance Specialist
Regulatory

Phone (201) 316-9288
kathryn.rosario@lonza.com

June 1, 2018

CONTAINS CONFIDENTIAL BUSINESS INFORMATION PROTECTED FROM DISCLOSURE UNDER FIFRA §10

SUBJECT: Application for Pesticide Label Registration, Non-Fast Track (A540)
NUGEN VALUE CQ 64, EPA Reg. No. 6836-*not yet assigned* - Primary
NUGEN VALUE CQ 32, EPA Reg. No. 6836-*not yet assigned* - Secondary

Dear Mr. Miederhoff:

Lonza is submitting applications to register two new end-use products as indicated above.

The names of the test substance used in these studies are not the requested EPA primary brand name. The table below describes the formulation of the Test Substance.

Test Substance ID	Formulation Name	EPA Reg. No.	CSF followed
DS 6771 Lot # 6070-014 Lot # 6066-180 and 6066-181	NUGEN VALUE CQ 64	6836-*not yet assigned*	Basic

Please find the enclosed documents in support of these registrations:

a. Application for Pesticide Registration;
b. PRIA fee payment receipts;
c. Transmittal Document;
d. The proposed product labels;
e. Certification with Respect to Label Integrity;
f. The proposed Confidential Statements of Formulation;
g. Formulator's Exemption form;
h. Certification with Respect to Citation of Data forms;
i. End-Use Data Matrix (Agency copies);
j. End-Use Data Matrix (Public copies);
k. The following 21 studies:

MRID Number	Study
50597001	NUGEN VALUE CQ 64: Product Identity and Composition; Description of Materials Used to Produce the Product; Description of Production Process; Description of Formulation Process; Description of the Formation of Impurities; Preliminary Analysis; Certified Limits; and Submittal of Samples (May 31, 2018) by Kathryn Rosario, Lonza; 6 pages, with 2 page confidential addendum.
50597002	Physical and Chemical Properties of DS6771 (May 2, 2018) by Katrina A. Staggemeier, Lonza GLP Services; OPPTS 830.6303/830.7300/830.7000/830.7100/830.6315; 48 pages.
50597003	NUGEN VALUE CQ 64: Product Physical and Chemical Properties – OPPTS Guideline 830.6302/6304/6313/6314/6316/6319/6321/7050/7200/7220/7370/7550/7560/7670/7840/7860/7950 (May 31, 2018) by Kathryn Rosario, Lonza; 6 pages, with 2 page confidential addendum.
50597004	Accelerated Storage Stability and Corrosion Characteristics of DS6771 (May 4, 2018) by Linda Hull, Lonza GLP Services; OPPTS 830.6317/830.6320; 29 pages.
50597005	AOAC Use Dilution Test *Enterobacter aerogenes* (March 7, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597006	AOAC Use Dilution Test *Escherichia coli* (March 7, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597007	AOAC Use Dilution Test *Klebsiella pneumoniae* (March 7, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597008	AOAC Use Dilution Test Methicillin-Resistant *Staphylococcus aureus* (March 7, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597009	AOAC Use Dilution Test *Staphylococcus epidermidis* (March 7, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597010	AOAC Use Dilution Test *Serratia marcescens* (March 7, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597011	AOAC Use Dilution Test *Shigella flexneri* (March 7, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597012	AOAC Use Dilution Test *Shigella sonnei* (March 7, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597013	AOAC Use Dilution Test *Streptococcus pyogenes* (March 7, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597014	AOAC Use Dilution Test *Pseudomonas aeruginosa* (January 3, 2018) by Kathryn D. Dormstetter, Microbac; OPPTS 810.2200; 32 pages.
50597015	AOAC Use Dilution Test *Salmonella enterica* (January 1, 2018) by Kathryn D. Dormstetter, Microbac; OPPTS 810.2200; 32 pages.
50597016	AOAC Use Dilution Test *Staphylococcus aureus* (January 1, 2018) by Kathryn D. Dormstetter, Microbac; OPPTS 810.2200; 32 pages.
50597017	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Virus: Herpes simplex virus type 1 (March 8, 2018) by Matt Cantin, Accuratus Lab Services; OPPTS 810.2200; 29 pages.
50597018	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Virus: Human Immunodeficiency virus type 1 (March 27, 2018) by Matt Cantin, Accuratus Lab Services; OPPTS 810.2200; 29 pages.
50597019	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Virus: Influenza A virus (March 8, 2018) by Matt Cantin, Accuratus Lab Services; OPPTS 810.2200; 29 pages.

Lonza

50597020	AOAC Use Dilution Test *Trichophyton interdigitale* (March 27, 2018) by Rana Rahmat, Microbac; OPPTS 810.2200; 30 pages.
50597021	EPA Hard Surface Mildew-Fungistatic Test. Test Organism: *Aspergillus niger* (ATCC 6275) (February 13, 2018) by Jamie Herzan, Accuratus Lab Services; 25 pages.

If you have any questions, please contact me at 201-316-9288 or by e-mail at kathryn.rosario@lonza.com.

Best regards

Kathryn Rosario
Regulatory Assurance Specialist

Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

EPA United States **Environmental Protection Agency** Washington, DC 20460

☒ **Registration** ☐ **Amendment** ☐ **Other:**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
6836-*Not Yet Assigned*	**Eric Miederhoff**	☒ None ☐ Restricted
4. Company/Product (Name) **NUGEN VALUE CQ 64**	PM# **31**	

5. Name and Address of Applicant *(Include ZIP Code)*
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401
PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW
☐ *Check if this is a new address*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☒ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application for New Pesticide Registration
Fee Category A540
Fee= $5107.00
PRE-PAID Fee on June 1, 2018
See Cover Letter for Details

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☒ Yes ☐ No	☐ Yes ☒ No	☒ Metal ☒ Plastic ☐ Glass ☐ Paper ☒ Other (Specify) bag-in-box
***Certification must be submitted**	If "Yes" Unit Packaging wgt. Various / No. per container Various	If "Yes" Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☒ Container	**Various**	☒ On Label ☒ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☒ Lithograph ☒ Paper glued ☒ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Kathryn Rosario	**Regulatory Assurance Specialist**	**201-316-9288**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	4. Typed Name	5. Date
Kathryn Rosario	**Regulatory Assurance Specialist**	**Kathryn Rosario**	June 1, 2018

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete White- EPA File Copy (original) Yellow- Applicant Copy

Pages 105-106 Confidential Statement of Formula may be entitled to confidential treatment